PATENT ABSTRACTS OF JAPAN

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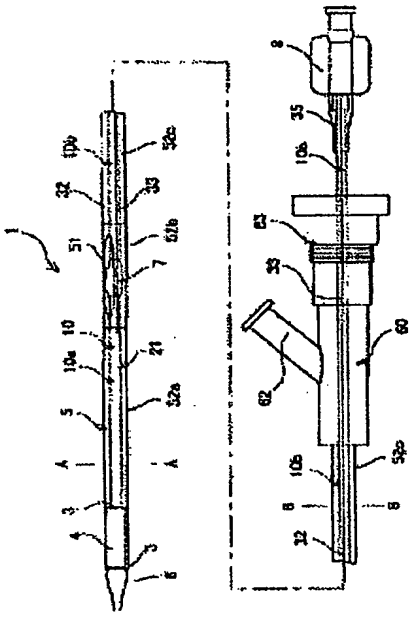
(54) INSTRUMENT FOR EXPANDING BIOLOGICAL ORGAN

(57)Abstract:
PROBLEM TO BE SOLVED: To provide an instrument for expanding biological organ, with which a break around the opening part of a sheath or lowering in operability does not occur.
SOLUTION: An instrument 1 for expanding biological organ is composed of a main body part 21 of shaft, expanding balloon 3, stent 4, catheter 10 for expansion provided with a guide wire lumen 15 opening one terminal on the top end of the main body part 21 of shaft and opening the other terminal on the intermediate part of the main body part 21 of shaft, and sheath 5 having a side hole 51 for inserting a guide wire, and is produced so that a side hole forming portion 52b of the sheath 5 can become higher rigidity than a top end part 52a of the sheath 5.



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CLAIMS

[Claim(s)]
[Claim 1]A tube shape shaft body part.
Folding provided in a tip part of this shaft body part, and an extensible balloon.
Stent which it is equipped with so that this balloon in the state where it was folded up may be wrapped entirely, and is extended by extension of this balloon.
A catheter for extension provided with a guide wire lumen in which one end carries out an opening at the tip of said shaft body part, and the other end carries out an opening in pars intermedia of said shaft body part.
A sheath which has a catheter lumen which stores said catheter for extension slidably.
Are the above the living body organic extension appliance implement which it had, and said sheath, It has a side hole which extends in shaft orientations for inserting a guide wire in said guide wire lumen provided in a position used as near the other end side opening of said guide wire lumen of said catheter for extension, A side hole formation part of this sheath serves as a high rigidity part whose rigidity is higher than a tip part of said sheath.

[Claim 2]Said catheter for extension is slidable to a state which the back end of said stent exposes in said sheath from a state where a tip of said stent of said catheter for extension was stored in said sheath, The living body organic extension appliance implement according to claim 1 which is equivalent to the length of said stent as for said side hole of said sheath, or is provided with shaft-orientations length beyond it.
[Claim 3]The living body organic extension appliance implement according to claim 1 or 2 currently produced with a resin material whose hardness is higher than a resin material which constitutes a tip part of said sheath from a tip part of said side hole formation part of said sheath to a base end of said sheath.
[Claim 4]The living body organic extension appliance implement according to claim 3 whose resin material with said high hardness is a with a Shore D hardness [of 55 or more] resin material.
[Claim 5]The living body organic extension appliance implement according to claim 3 or 4 whose resin material with said high hardness is polyester or polyamide.
[Claim 6]The living body organic extension appliance implement according to any one of claims 1 to 5 by which a tip part of said sheath is produced with a with a Shore D hardness of 50 or less resin material.
[Claim 7]The living body organic extension appliance implement according to any one of claims 1 to 6 whose resin material which constitutes a tip part of said sheath is polyester or polyamide.
[Claim 8]The living body organic extension appliance implement according to any one of claims 1 to 7 with which said side hole formation part has a metal reinforcing member.
[Claim 9]The living body organic extension appliance implement according to claim 8 which is a tubular member in which said reinforcing member has two or more openings.
[Claim 10]The living body organic extension appliance implement according to claim 8 in which said reinforcing member is a wire-like member.
[Claim 11]A living body organic extension appliance implement given in either of 1 thru/or 10 by which said sheath consists of a sheath outer layer and a sheath inner layer formed inside this sheath outer layer, and this sheath inner layer is produced with fluororesin material.
[Claim 12]The living body organic extension appliance implement according to claim 11 currently produced so that said inner layer may project from said sheath outer layer tip.
[Claim 13]The living body organic extension appliance implement according to any one of claims 1 to 12 provided with a locking mechanism which fixes said catheter for extension in arbitrary positions to said sheath.
[Claim 14]The living body organic extension appliance implement according to any one of claims 1 to 13 provided with a stopper which said catheter for extension is formed in the tip side rather than said stent, and prevents movement in the direction of a tip of said sheath.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention]This invention relates to the living body organic extension appliance implement used for the improvement of the narrow segment formed in living body organs, such as an organ of a blood vessel, a bile duct, a trachea, an esophagus, an urethra, and others. It is related with the possible living body organic extension appliance implement of carrying especially the strangulation lesion in endovascular treatment, and the stent for living body organic extension mainly performed after the PTCA enforcement in strangulation parts, such as the heart and the blood vessels, to the purpose living body organic part to the basis of safety and smooth operativity.
[0002]
[Description of the Prior Art]The living body organic dilation which detains the stent in the narrow segment of living body lumina, such as an organ of a blood vessel, a bile duct, an esophagus, a trachea, an urethra, and others, or the abdominal cavity, and secures a lumen or abdominal cavity space conventionally is performed. As stent used for this, there are balloon expander bull stent and self expander bull stent by the function and the detention method. In order for expanded function not to have the balloon expander bull stent in the stent itself and to detain the stent in a target part, For example, after inserting the stent with which the expansion body (balloon) was equipped to a target part, make a balloon extend, make the stent extend with the extension power of a balloon (plastic deformation), and it is made to stick to the inner surface of a target part, and fixes. As a living body organic extension appliance implement detained in a target part, the balloon expander bull type stent, The stent feeding system which consists of a sheath which carries out dilation balloon catheter entire covering with the dilation balloon catheter which has an extended balloon which extends the stent to JP,H6-23507,A, and what is called a rapid exchange system are indicated. This stent feeding system has a guide wire lumen which carries out an opening in the tip and pars intermedia of a dilation balloon catheter, and the side hole formed in sheath pars intermedia.
A guide wire can be inserted in the opening formed in catheter pars intermedia through the side hole of a sheath from the middle of the sheath, and stent operation can be performed.

[0003]
[Problem(s) to be Solved by the Invention]However, in the rapid exchange system of the above-mentioned composition, when a guide wire contacts a side hole by receipts-and-payments operation of a guide wire, there is a possibility that the circumference of a sheath side hole may fracture. Since the sheath side hole formation part is more nearly vulnerable than other portions, there is a possibility that the circumference of a side hole may produce a fracture. The torque and pressing force (if it puts in another way pusher kinky thread tee) which were given in the sheath side hole formation part at the rear end part side of a living body organic extension appliance implement during stent placement operation are absorbed, and there is a possibility of producing the fall of operativity. Then, this invention solves the above-mentioned problem.
The purpose is to provide a living body organic extension appliance implement with the fall of operativity, such as a fracture near a sheath opening, arising [little].

[0004]
[Means for Solving the Problem]Folding and an extensible balloon in which what attains the above-mentioned purpose was provided in a tube shape shaft body part and a tip part of this shaft body part, Stent which it is equipped with so that this balloon in the state where it was folded up may be wrapped entirely, and is extended by extension of this balloon, It is a living body organic extension appliance implement provided with a catheter for extension provided with a guide wire lumen in which one end carries out an opening at the tip of said shaft

body part, and the other end carries out an opening in pars intermedia of said shaft body part, and a sheath which has a catheter lumen which stores said catheter for extension slidably. And said sheath is provided with a side hole which extends in shaft orientations for inserting a guide wire in said guide wire lumen provided in a position used as near the other end side opening of said guide wire lumen of said catheter for extension, A side hole formation part of this sheath serves as a high rigidity part whose rigidity is higher than a tip part of said sheath.

[0005]Said catheter for extension is slidable to a state which the back end of said stent exposes in said sheath from a state where a tip of said stent of said catheter for extension was stored in said sheath, As for said side hole of said sheath, it is preferred equivalent to the length of said stent or to have shaft-orientations length beyond it. It is preferred to be produced with a resin material whose hardness is higher than a resin material which constitutes a tip part of said sheath from a tip part of said side hole formation part of said sheath to a base end of said sheath. As for a resin material with said high hardness, it is preferred that it is a with a Shore D hardness [of 55 or more] resin material. As for a resin material with said high hardness, it is preferred that they are polyester or polyamide. As for a tip part of said sheath, it is preferred to be produced with a with a Shore D hardness of 50 or less resin material. As for a resin material which constitutes a tip part of said sheath, it is preferred that they are polyester or polyamide.

[0006]As for said side hole formation part, it is preferred to have a metal reinforcing member. As for said reinforcing member, it is preferred that it is a tubular member which has two or more openings. As for said reinforcing member, it is preferred that it is a wire-like member. Said sheath consists of a sheath outer layer and a sheath inner layer formed inside this sheath outer layer, and, as for this sheath inner layer, being produced with fluororesin material is preferred. As for said inner layer, it is preferred to be produced so that it may project from said sheath outer layer tip. It is preferred to have a locking mechanism which fixes said catheter for extension in arbitrary positions to said sheath. As for said catheter for extension, it is more preferred than said stent to have a stopper which is formed in the tip side and prevents movement in the direction of a tip of said sheath.

[0007]

[Embodiment of the Invention]The living body organic extension appliance implement of this invention is explained using the preferred embodiment shown in Drawings. Drawing 1 the front view of one working example of the living body organic extension appliance implement of this invention and drawing 2, The expanded sectional view near the tip of the living body organic extension appliance implement shown in drawing 1 and drawing 3, The expanded sectional view of the central joining section of the living body organic extension appliance implement shown in drawing 1 and drawing 4, The A-A line sectional view of drawing 1 and drawing 5 the B-B line sectional view of drawing 1 and drawing 6, The C-C line sectional view of drawing 3 and drawing 7 the D-D line sectional view of drawing 3 and drawing 8, The expanded sectional view of the branch hub of the living body organic extension appliance implement shown in drawing 1 and drawing 9 are explanatory views for the expanded sectional view of the rear end part of the catheter for extension of the living body organic extension appliance implement shown in drawing 1 and drawing 10 to describe other working example of the living body organic extension appliance implement of this invention.

[0008]The living body organic extension appliance implement 1 of this invention The tube shape shaft body part 21, Folding and the extensible balloon 3 which were provided in the tip part of the shaft body part 21, The stent 4 which it is equipped with so that the balloon 3 in the state where it was folded up may be wrapped entirely, and is extended by extension of the balloon 3, It has the catheter 10 for extension provided with the guide wire lumen 15 in which one end carries out an opening at the tip of the shaft body part 21, and the other end carries out an opening in the pars intermedia of the shaft body part 21, and the sheath 5 which has the catheter lumen 50 which stores the catheter 10 for extension slidably. And the sheath 5 is provided with the side hole 51 which extends in the shaft orientations for inserting the guide wire 100 in the guide wire lumen 15 provided in the position used as near the other end side opening of the guide wire lumen 15 of the catheter 10 for extension, The side hole formation part 52b of the sheath serves as a high rigidity part whose rigidity is higher than the tip part 52a of the sheath 5.

[0009]The living body organic extension appliance implement 1 of this invention is what is called what is called a rapid exchange type, It has the guide wire lumen 15 which it was provided in catheter 10 inside for extension as shown in drawing 1 and drawing 3, and carried out the opening (other end side opening 36) in the tip and pars intermedia of the catheter 10 for extension, and the side hole 51 for guide wire insertion formed in sheath pars intermedia. By such composition, the living body organic extension appliance implement 1 can insert a guide wire in the opening (other end side opening 36) formed in catheter pars intermedia through the side hole of a sheath from the middle (pars intermedia) of the sheath, and can be performing stent operation.

[0010]As shown in drawing 1, the living body organic extension appliance implement 1 The shaft body part 21,

The stopper 6 formed at shaft body part 21 tip, and the balloon 3 for stent extension provided in the tip part of the shaft body part 21, It consists of the catheter 10 for extension which consists of the stent 4 with which it was equipped on the balloon 3, and the hub 8 attached to the rear end part of the shaft body part 21, the sheath 5 which wraps the catheter 10 entirely, and the branch hub 60 attached to the rear end part of the sheath 5.
[0011]The catheter 10 for extension consists of the tip side shaft part 10a and the back end side shaft part 10b, and the tip side shaft part 10a and the back end side shaft part 10b are joined via the junction connector 7, as shown in drawing 1 and drawing 3. The catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes in the sheath 5 from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5. The inner tube 12 with which the tip side shaft part 10a forms the guide wire lumen 15 as shown in drawing 2 and drawing 3, It consists of the balloon 3 provided in the tip part of the inner tube 12, the stent 4 with which the periphery of the balloon 3 was equipped, and the outer tube 13 which is provided in the back end side from the balloon 3, wraps the inner tube 12 entirely, and forms the lumen 16 for balloon extension between the outside surfaces of the inner tube 12. And the tip side shaft part 10a is slidably stored in the catheter lumen 50 of the sheath 5. And the rear end part of the tip side shaft part 10b is joined to the tip part of the junction connector 7.
[0012]The balloon 3 has the tip side joined part 3a and the back end side joined part 3b, as shown in drawing 2, the tip side joined part 3a is fixed to the position by the side of the back end a little from the tip of the inner tube 12, and the back end side joined part 3b is being fixed at the tip of the outer tube 13. The balloon 3 is open for free passage with the lumen 16 for balloon extension near a base end. And the stopper 6 is being fixed at the tip of the inner tube 12 so that the tip part of the tip side joined part 3a of the balloon 3 may be wrapped entirely. The stopper 6 is annularly formed with the spring material, and his outer diameter of a rear end part is almost equal to the inside diameter of the sheath 5, or he is a little large. Thus, by having the stopper 6, movement in the direction of a tip of the stent 4 is prevented, and the stent 4 is not omitted from a catheter during stent placement operation. The stopper 6 is the tapered shape whose diameter is reduced gently-sloping toward a tip. By forming in this way, the derivation function to a narrow segment can be given to the stopper 6, and insertion to the narrow segment of a living body organ becomes easy about a stent mounting section.
[0013]And as the inner tube 12, an outer diameter is 0.45-0.8 mm preferably 0.35-1.0 mm, and an inside diameter is 0.35-0.7 mm preferably 0.2-0.9 mm. As the outer tube 13, an outer diameter is 0.8-1.1 mm preferably 0.6-1.5 mm, and an inside diameter is 0.7-1.0 mm preferably 0.5-1.4 mm. As the sheath 5, an outer diameter is 1.2-1.5 mm preferably 0.8-1.8 mm, and an inside diameter is 1.0-1.3 mm preferably 0.5-1.5 mm. As a formation material of the inner tube 12, the outer tube 13, and the stopper 6, What has a certain amount of flexibility is preferred, for example, thermoplastics, such as polyamide, polyester, polyolefine (bridge construction or a partial bridge construction thing is also included), polyvinyl chloride, and polyurethane, silicone rubber, latex rubber, etc. can be used, and it is the desirable above-mentioned thermoplastics.
[0014]The balloon 3 can be folded up and can be in the state where it was folded up by the periphery of the inner tube 12, in the state where it is not made to extend. The balloon 3 has the extensible part 31 which became a cylindrical section (preferably cylinder part) of the diameter of the same mostly so that the stent 4 with which it is equipped could be extended. The above-mentioned approximate circle pipe portion may not be a perfect cylinder, but may be a multiple pillar-like thing. and the balloon 3 -- above -- the tip side joined part 3a -- the inner tube 12 -- again -- the back end side joined part 3b -- the tip of the outer tube 13 -- adhesives or thermal melting arrival -- liquid -- it has adhered densely. The balloon 3 forms the growth space 3c between the inner surface of the balloon 3, and the outside surface of the inner tube 12, as shown in drawing 2. This growth space is open for free passage with the lumen 16 for extension in that perimeter in the rear end part. Thus, since the back end of the balloon 3 is open for free passage with the lumen for extension which has comparatively large capacity, it is more sure than the lumen 16 for extension. [the fluid for extension into a balloon]
[0015]As a formation material of the balloon 3, what has a certain amount of flexibility is preferred, for example, thermoplastics, such as polyolefine, polyvinyl chloride, polyamide, polyurethane, polyester, and poly ant rain sulfide, silicone rubber, latex rubber, etc. can be used. It is preferred that it is the material which can be extended especially, and the balloon 3 has the preferred thing which has high intensity and extension power and by which biaxial extension was carried out. As a size of the balloon 3, the outer diameter of a cylinder part (extensible part 31) when extended is 2.5-4.0 mm preferably 1.5-5.0 mm, and length is 10-40 mm preferably 5-50 mm. The outer diameter of the tip side joined part 3a is 0.7-1.0 mm preferably 0.5-1.5 mm, and length is 1.0-1.3 mm preferably 1-5 mm. The outer diameter of the back end side joined part 3b is 1.0-1.5 mm preferably 0.8-1.6 mm, and length is 2-4 mm preferably 1-5 mm.
[0016]And the tip side imaging marker 17 is being fixed to the outside surface of the position which becomes the shaft body part 21 (this working example inner tube 12) with near the tip inside the extensible part 31 of the

balloon 3. Similarly, the back end side imaging marker 18 is being fixed to the outside surface of the position which becomes the shaft body part 21 (this working example inner tube 12) with near the back end inside the extensible part 31 of the balloon 3. As for an imaging marker, it is preferred to form with radiopacity materials (for example, gold, platinum, tungsten, those alloys, or a silver-palladium alloy etc.). The position of the position of the tip of the extensible part 31 of the balloon 3 and the back end and by extension, the tip of the stent 4, and the back end can be checked by X ray imaging by doing in this way.

[0017]The stent 4 used for the living body organic extension appliance implement 1 of this invention, If it puts in another way when the power which is formed in an abbreviated tubular body, has a diameter for insertion to the living body, and spreads in the method of the outside of a radial direction from the inside of a tubular body is added, when the balloon 3 is extended, it will be extensible (extension is possible), and will be what is called balloon expander bull stent. As the stent 4, as shown in drawing 14, the component 22 of the shape of an approximately ellipse to which the center section was annoyed by the shaft orientations of the stent 4 for a long time, or polygonal shape, for example, it being mostly arranged on an approximate circle circumference in an equiangular distance to the medial axis of the stent 4, and. Between the adjoining parts (flank) of the circumferencial direction of a component consists of the annular unit 24 (24a, 24b, 24c, 24d, 24e, 24f) connected in the terminal area 23 (23a, 23b, 23c, 23d). And two or more annular units 24a, 24b, 24c, 24d, 24e, and 24f are located in a line with the shaft orientations of the stent 4. What at least one terminal area 23 of the annular unit 24 which adjoins the terminal area 23 of the one annular unit 4 is connected to by the connecting part 25 (25a, 25b, 25c, 25d, 25e) is preferred. However, the shape of the stent 4 is not limited to such a thing, and can use publicly known things, such as mesh shape.

[0018]What has a certain amount of biocompatibility as a formation material of the stent 4 is preferred, for example, stainless steel, tantalum or a tantalum alloy, and the platina ****** can consider a platinum alloy, gold or a gold alloy, a cobalt base alloy, etc. After producing stent shape, noble metal plating (gold, platina) may be carried out. As stainless steel, SUS316L which has corrosion resistance most is preferred. About 0.8-1.5 mm is preferred for the diameter at the time of un-extending of the stent 4, and its 0.9-1.2 mm is especially more preferred.

[0019]The back end side shaft part 10b consists of the shaft tube 32 and the hub 8 fixed to the back end of the shaft tube 32, as shown in drawing 1 and drawing 3. And the back end side shaft part 10b is slidably stored in the catheter lumen 50 of the sheath 5. And the tip part of the back end side shaft part 10b is joined to the rear end part of the junction connector 7. Into the shaft tube 32, as shown in drawing 1 and drawing 7, the rigid grant object 33 is inserted, and the rigid grant object 33 is fixed to the shaft tube 32 in a rear end part, and a tip, From the tip of the shaft tube 32, it projected, the junction connector 7 mentioned later was penetrated, and it has extended in the tip side shaft. In other words, in this working example, the tip part of the rigid grant object 33 has reached in the lumen 16 for balloon extension between the inner tube 12 of a tip side shaft, and the outer tube 13.

[0020]The rigid grant object 33 is prolonged in the tip side in the inside from the end face of the shaft tube 32. The rigid grant object 33 is being fixed to the shaft tube 32 or the hub 8 by only the base end, and so that it may not become an obstacle of a curve of the shaft body part 21 on other portions and a concrete target. It is being fixed to neither the inside except the base end of the shaft tube 32 nor junction connector 7 portion nor the tip side shaft part (the inner tube 12 and the outer tube 13). The rigid grant object 33 prevents meandering within that the degree of pole of the shaft tube 32 in a crookedness part bends, and the blood vessel of the shaft tube 32, without reducing the flexibility of the shaft tube 32 not much. As for the rigid grant object 33, being formed with the line object is preferred. As a line object, it is desirable, and it is elastic metal, such as 0.1-1.0-mm stainless steel, a superelastic alloy, etc. preferably that it is a metal wire, and 0.05-1.5 mm of wire sizes are the high tension stainless steel for springs, and a superelastic alloy line especially preferably.

[0021]Generally a superelastic alloy here is called shape memory alloy, and shows superelasticity at living body temperature (near 37 **) at least. Superelastic alloys, such as Ti-Ni alloy of 49 -53-atom %nickel, Cu-Zn alloy of 38.5 to 41.5-% of the weight Zn, a Cu-Zn-X alloy (X=Be, Si, Sn, aluminum, Ga) of 1-10 % of the weight X, and nickel-aluminum alloy of 36 to 38 atom %aluminum, are used especially suitably preferably. Especially, the above-mentioned Ti-Ni alloy is desirable. . [whether some Ti-Ni alloys are used as the Ti-nickel-X alloys (X=Co, Fe, Mn, Cr, V, aluminum, Nb, W, B, etc.) replaced by 0.01-10.0 atom %X, and] Or a mechanical property is changeable suitably by choosing the conditions of using some Ti-Ni alloys as the Ti-nickel-X alloy (X=Cu, Pb, Zr) replaced by 0.01-30.0 atom %X and a cold working rate, or/and final heat treatment. A mechanical property is changeable suitably by choosing the conditions of a cold working rate and/or final heat treatment using the above-mentioned Ti-nickel-X alloy.

[0022]The shaft tube 32 is fixing the rigid grant object 33 in a end face, and the back end of this shaft tube 32 is being further fixed to the tip part of the hub 8. The tube 35 for kink prevention is attached to the outside

surface of the boundary part of the hub 8 and the shaft tube 32 so that both may be covered. The rear end part of the hub 8 is the terminal area 34 of the fluid transfer pipet implement for balloon extension (for example, syringe). As the shaft tube 32, an outer diameter is 0.6-1.3 mm preferably 0.5-1.5 mm, and an inside diameter is 0.5-1.2 mm preferably 0.3-1.4 mm. What has a certain amount of flexibility as a formation material of the shaft tube 32 is preferred, for example, polyolefine (for example, polyethylene and polypropylene.) Ethylene propylene rubber, an ethylene-vinylacetate copolymer, etc. can use thermoplastics, such as polyvinyl chloride, a polyamide elastomer, polyimide, and polyurethane, silicone rubber, latex rubber, etc., and it is the desirable above-mentioned thermoplastics. A stainless steel tube may be used as a formation material of the shaft tube 32, without using the rigid grant object 33.

[0023]The junction connector 7 is prolonged from a tip center in shaft orientations to a center section, as shown in drawing 3, It has an inner-tube insertion passage which curves from a center section and arrives at the lateral surface by the side of the back end, the rear end part of the inner tube 12 penetrates the inside of this insertion passage, and the rear end part of the inner tube 12 which projects from the side of the junction connector 7 forms guide wire introduction RO 36 (other end side opening 36). The opening of the other end side opening 36 is formed toward the end face side slanting upper part of drawing 3. Direction of an opening may not be restricted to the thing of working example, but may be formed toward right above drawing 3. The fluid distribution ways 37a and 37b for balloon extension which extend in a end face from a tip are formed in the junction connector 7. By this circulation way, the lumen 16 for balloon extension currently formed of between the inner tube 12 and the outer tubes 13 and the lumen 16 for balloon extension currently formed in the shaft tube 32 are open for free passage. The rigid grant object conduction passage penetrated to the end face is formed in the junction connector 7 from the tip as mentioned above, and the rigid grant object 33 has penetrated this.

[0024]The sheath 5 is provided with the following.

As shown in drawing 1, drawing 2, and drawing 3, it is produced by tube shape, and it is the catheter lumen 50 to an inside.

It is the side hole 51 to pars intermedia.

Where the tip of the stent 4 is stored in the catheter lumen 50, the tip part of the stent 4 and the stopper's 6 back end touch mostly. The rear end part of the sheath 5 is joined to the tip part of the branch hub 60. The catheter lumen 50 serves as a passage which stores the catheter 10 for extension slidably as shown in drawing 1 and drawing 3. In other words, the catheter lumen 50 is a passage which enables insertion of the catheter 10 for extension, The tip of the catheter 10 for extension was projected from the tip of the catheter lumen, i.e., the tip of a sheath, and the base end of the catheter 10 for extension is projected from the back end of the catheter lumen, i.e., the back end of a sheath.

[0025]The side hole 51 is formed in order to insert in the guide wire 100 in the guide wire lumen 15. The guide wire 100 is inserted in the other end side opening 36 via the side hole 51, and is introduced in the guide wire lumen 15. The side hole 51 is produced as an ellipse-like opening prolonged in shaft orientations, as shown in drawing 1 and drawing 3, and it is formed so that it may be open for free passage with the catheter lumen 50 in the position used as the other end side opening 36 neighborhood which is a guide wire loading slot of the guide wire lumen 15.

[0026]The catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes in the sheath 5 from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5, The side hole 51 of the sheath 5 is equivalent to the length of the stent 4, or is provided with the shaft-orientations length beyond it. Thus, when the side hole 51 has a certain amount of length in shaft orientations, exposure of the other end side opening 36 (guide wire loading slot) is completely attained out of a sheath in the back end of the stent 4 in the state where it was located in the side hole 51. In the state where the tip of the stent 4 was specifically stored in the sheath as shown in drawing 11, The end face 36a of the other end side opening 36 is located in the tip side from the end face of the side hole 51, and the end face 36a of the other end side opening 36 is located in the end face side from the tip of the side hole 51 in the state where the stent 4 was thoroughly exposed from sheath 5 tip as shown in drawing 12. In this state, it is preferred to be constituted so that the tip 36b of the other end side opening 36 may also be located in the end face side from the tip of the side hole 51. For this reason, since the guide wire 100 cannot contact easily during stent placement operation in the side hole 51, it is hard to damage a side hole formation part.

[0027]At the time of insertion in the living body, the living body organic extension appliance implement 1, In [are in the state where most stopper 6 portions of the catheter for extension are exposed, and the stent 4 is not exposed at all from the tip of the sheath 5 as shown in drawing 1, and] this state, The catheter 10 for extension is being fixed by the catheter locking mechanism 63 of the branch hub 60 established in the rear end part of the sheath 5 mentioned later. For this reason, unless the catheter locking mechanism 63 is canceled, the state of drawing 1 is maintained, and the inside of a sheath cannot be slid on the catheter for extension. In the state

where it is not locked by the catheter locking mechanism 63 in the sheath 5, the catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5.

[0028]The sheath 5 is formed from the sheath outer layer 52 and the sheath inner layer 53 formed inside the sheath outer layer 52, as shown in drawing 1 – drawing 3, drawing 10 – drawing 12. The sheath outer layer 52 and the sheath inner layer 53 are unified. And as shown in drawing 1 and drawing 2, the tip of the sheath outer layer 52 and the tip of the sheath inner layer 53 are produced so that it may become the almost same position as the shaft orientations of a sheath. As shown in drawing 8, the end face of the sheath outer layer 52 and the sheath inner layer 53 is joined to the tip part of the branch hub 60 by adhesives, thermal melting arrival, etc. Although produced as a two-layer structure of an outer layer and a inner layer in working example, it may be the multilayer structure of three or more layers. A sheath may be layer structure.

[0029]As for the sheath inner layer 53, being formed with fluororesin material is preferred. As a fluororesin material, polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), etc. can be used and it is polytetrafluoroethylene preferably. By producing a sheath inner layer with fluororesin material, it becomes easy to slide on a catheter lumen wall, and the catheter for extension slides easily in a catheter lumen. As for the sheath outer layer 52, it is preferred to be produced with the resin which has flexibility to some extent so that the bent lumen in the living body can be gone on easily. As a component of the sheath outer layer 52, thermoplastics, such as polyamide, polyester, polyolefine (bridge construction or a partial bridge construction thing is also included), polyvinyl chloride, and polyurethane, etc. can be used, and it is the desirable above-mentioned thermoplastics, for example.

[0030]The side hole formation part (side hole surrounding portion) of the sheath 5 serves as a high rigidity part whose rigidity is higher than the tip part of the sheath 5. It is hard to produce the fall of the operativity by absorption of the torque and pressing force (if it puts in another way pusher kinky thread tee) which were given to the rear end part side of the living body organic extension appliance implement in a side hole formation part, such as a fracture of a side hole formation part, by constituting in this way that it is [under / stent placement operation / setting]. It is produced with the resin material whose hardness is specifically higher than the resin material which constitutes the tip part 52a of the sheath 5 (sheath outer layer 52) from the tip part of the side hole formation part 52b of the sheath 5 (sheath outer layer 52) to the base end 52c of the sheath 5 (sheath outer layer 52).

[0031]As for the resin material with high hardness, it is preferred that it is a with a Shore D hardness [of 50 or more] resin material, and it is especially preferred that it is the Shore D hardness of 55 or more. As for the resin material with high hardness, it is preferred that they are polyester and polyamide. As polyester system resin, polyethylene terephthalate, polybutylene terephthalate, etc. are preferred and polyethylene terephthalate preferably. As polyamide system resin, nylon 6, Nylon 66, Nylon 46, Nylon 11, Nylon 12, etc. are preferred. As for the tip part 52a of a sheath, it is preferred to be produced with a with a Shore D hardness of 50 or less resin material. Thereby, the tip part of a sheath becomes what has pliability, and can advance the complicated living body lumen smoothly. The resin material which constitutes the sheath tip part 52a, a polyester elastomer and an olefin system elastomer (for example, a polyethylene elastomer.) A polypropylene elastomer, a polyamide elastomer, a styrene system elastomer. for example, styrene butadiene styrene copolymer and styrene isoprene styrene copolymer. Flexible resin, such as styrene ethylene butylene styrene copolymer, a polyamide elastomer, a polyester elastomer, and a thermoplastic fluorinated elastomer, is preferred.

[0032]The sheath tip part 52a the sheath 5, for example by a with a Shore D hardness of 50 or less polyamide elastomer. and the side hole circumference 52b -- a with a Shore D hardness [of 50 or more] polyamide elastomer -- and the sheath base end 52c can produce by a with a Shore D hardness [of 50 or more] polyamide elastomer. Even if a guide wire is inserted in the other end opening 36 through the side hole 51 and it performs stent placement operation by constituting a sheath as mentioned above, The side hole formation part 52b does not have a possibility of producing the fall of the operativity resulting from the torque and pressing force (if it puts in another way pusher kinky thread tee) which were given to the rear end part side of a living body organic extension appliance implement being absorbed by the side hole formation part 52b, without fracturing. In working example, after producing the tip part 52a of the sheath 5, the side hole formation part 52b of the sheath 5, and the base end 52c of the sheath 5 as respectively different component part, join and unify, and are producing the sheath, but. Not the thing restricted to this but the side hole formation part 52b and the base end 52c are produced as one component part, it may join to the tip part 52a, and a sheath may be produced. Thermal melting arrival, adhesives, etc. can perform junction.

[0033]As for the outside surface of the sheath tip part 52a, it is preferred that hydrophilization treatment is performed. As hydrophilization treatment, it can carry out by coating a sheath outside surface with hydrophilic substances (for example, water-soluble silicone, PVA, PVP, etc.). As a size of a sheath, 1.2-1.5 mm and an inside

diameter are [1.0-1.3 mm and the length of an outer diameter] 1200-1400 mm 800-1600 mm 0.8-1.5 mm preferably 0.8-1.8 mm. As a size of the side hole 51 of a sheath, the lay length to which the shaft orientations of 15-50 mm and a sheath and the length of the shaft orientations of a sheath cross at right angles preferably 5-80 mm is 0.35-0.7 mm preferably 0.1-1.0 mm.

[0034]The side hole formation part 52b of the sheath 5 may have the metal reinforcing member 54 like the living body organic extension appliance implement of working example shown in drawing 10. Absorption of the torque in the fracture of the sheath side hole 51 circumference and a side hole formation part, etc. can be prevented by providing a metal reinforcement member in a side hole formation part. As for the metal reinforcing members 54, it is preferred that it is a tubular member which has two or more openings 541 as shown in drawing 13. The metal reinforcement member is mostly produced as a tubular member of the diameter of the same, and has the opening 541 elliptical [two or more] prolonged along the shaft orientations of a tubular member. As an opening configuration, it may not be restricted to elliptical, but may be rectangular form etc. The tubular member is installed so that one opening may lap with the side hole 51 among two or more openings of a tubular member, while contacting the inner layer 53 at the sheath outer layer wall of the side hole formation part 52b. As how to embed a tubular member, the outer layer by the side of a end face is formed at portions other than a tip end part on that with which the inner layer formation material was covered on the surface of rodding, It can carry out by inserting in and attaching a tubular member on the base end of an outer layer agenesis portion, covering resin for side hole formation parts on it, and producing further by covering resin for tip part formation parts on the tip part of an outer layer agenesis portion.

[0035]It may be produced by the wire-like member although not illustrated as a metal reinforcement member. In the case of a wire-like member, it is preferred to embed two or more linear shape wires along the shaft orientations of a sheath at the sheath wallplate of the circumference 52b of a side hole. A wire-like member may be produced a coiled form or in the shape of a braid, and it may also be embedded at the sheath wall of the side hole 51 neighborhood. Metal reinforcing members may be formed combining a linear shape wire and a coiled wire. It is preferred to use the same material as the rigid grant object 33 as a component of a metal reinforcement member. As a size of the metal reinforcing members of a tubular member, length is 20-60 mm preferably 10-90 mm, an inside diameter is 1.1-1.4 mm preferably 0.9-1.6 mm, and the thickness of a wallplate is 0.05-0.10 mm preferably 0.03-0.15 mm. As a wire size of the metal reinforcement member of a wire-like member, it is 0.03-0.15 mm and is 0.05-0.10 mm preferably.

[0036]As for a sheath outside surface, it is preferred that hydrophilization treatment is performed. By this, when a sheath moves a living body lumen or the abdominal cavity, a wall is made damage, and it is a stake. As hydrophilization treatment, it can carry out by coating a sheath outside surface with hydrophilic substances (for example, water-soluble silicone, PVA, PVP, etc.). Like the living body organic extension appliance implement 70 of working example shown in drawing 15, the sheath 5 may be produced so that the sheath inner layer 73 may project in the tip side from the sheath outer layer 72. Thus, while being able to make thickness of a sheath thin by producing so that it may project in the tip side, the outer diameter of the tip part of a sheath can be made into a byway. It is preferred to be produced with fluororesin as such a sheath inner layer 73, as mentioned above. It is preferred that hydrophilization treatment is carried out to the outside surface of the projection part of a sheath inner layer. The length for the tip projection of the sheath inner layer 73 is 10-40 mm preferably 0.5-50 mm. Except for near a side hole formation part, it may produce with fluororesin among the inner layers 73 of a sheath.

[0037]Next, the branch hub 60 is explained using drawing 8. The injection port 62 for priming provided so that it might branch from the body part 61 in the branch hub body part 61 and the center section of the branch hub body part 61 as the branch hub 60 was shown in drawing 8, It consists of the catheter locking mechanism 63 which is provided in the rear end part of the branch hub 60, and restricts movement of the catheter for extension, and the catheter lumen 64 for extension provided from the tip of a branch hub to the end face. The diameter of a catheter lumen of the back end 65 of the branch hub 60 is produced smaller than the tip part of the hub 8, and the tip part of the hub 8 is not moving at the tip from near the back end of the branch hub 60. The sheath rear end part is joined to the tip part of the branch hub 60. As for the rear end part of the sheath 5, it is preferred to be fixed to the end face side by the 1-5-mm position from the tip part of the branch hub 60.

[0038]The locking mechanism 63 consists of the elastic body 631 which pinches the base end of the catheter 10 for extension by compression, and the operation body 632 which compresses the elastic body 631. By having the locking mechanism 63, the catheter 10 for extension is fixed in arbitrary positions to the sheath 5. The elastic body 631 is installed in the crevice 611 established in the base end of the branch hub body part 61, and the lumen 631a which forms a part of catheter lumen 64 is formed in the inside of the elastic body 631. The inside diameter of the body part crevice 611 is produced somewhat more greatly than elastic body 631 outer diameter, and enables diameter expansion to the radial direction of the elastic body at the time of the elastic body 631

being compressed by the operation body 632. The lumen 631a of the elastic body 631 is produced by the shape where a part of two approximate sphere shape overlapped shaft orientations, and both ends and a center section are reducing the diameter of it. As long as the lumen 631a is not restricted to the shape of working example mentioned above and locks the catheter for extension exactly, it may be what kind of shape.

[0039]The operation body 632 is formed in the elastic body pressing part 632a projected to the tip side in the center section, and its periphery, and consists of the rear end part 611a of the crevice 611, the screwing part 632b to screw, and the support part 632c for supporting, when it is formed in the periphery of the screwing part 632c and the operation body 632 is rotated. The lumen 632d which forms a part of catheter lumen 64 is formed in the inside of the elastic body pressing part 632a. The tip side portion of the elastic body pressing part 632a is stored in the body part crevice 611, as shown in drawing 8, and it has compressed the elastic body 631 by movement at the tip of an operation body. When the operation body 632 is rotated and it screws in the tip side to the branch hub 60 by the above composition, the tip of the elastic body pressing part 632a contacts the back end of the elastic body 631, and the elastic body 631 is further compressed by shaft orientations by screwing the operation body 632 in the tip side. And a lumen 631a inside diameter becomes small, and the base end of the catheter 10 for extension is eventually fixed with the elastic body 631 as it compresses. Release of the locking mechanism 63 is performed by rotatably operating contrary to the above.

[0040]As a component of the branch hub 60 except the elastic body 631, polycarbonate, polyolefine (for example, polyethylene, polypropylene, ethylene-propylene copolymer), and styrene resin [-- for example, Polystyrene, MS resin (methacrylate styrene copolymer), and MBS resin (methacrylate butylene-styrene copolymer)], polyester, etc. can be used. As a component of the elastic body 631, urethane rubber, silicone rubber, Crude rubber, such as synthetic rubbers, such as butadiene rubber, and latex rubber, an olefin system elastomer. (For example, a polyethylene elastomer, a polypropylene elastomer), a polyamide elastomer and a styrene system elastomer (for example, styrene butadiene styrene copolymer.) Styrene isoprene styrene copolymer, styrene ethylene butylene styrene copolymer, polyurethane, a urethane system elastomer, a fluoro-resin system elastomer, etc. are preferred.

[0041]In working example of this invention, the sheath 5 is not restricted to this, although directly fixed to the tip part of the branch hub 60, it may attach a hub to sheath 5 rear end part, and may join a branch hub to a sheath by screwing it with the tip part of the branch hub 60. Where the stent 4 is stored in a sheath (state which lengthened the catheter 10 to the end face side), the rear end part of the branch hub 60 is being preferably fixed in a 50-100-mm position 10-200 mm from the tip part of the tube 35 for kink prevention.

[0042]Next, an operation of the living body organic extension appliance implement of this invention is explained. As shown in drawing 11, where stent 4 tip is stored in the sheath 5, the opening end face 36a of the other end side opening 36 is located in the tip close-attendants side of side hole 51 end face. And the catheter 10 for extension is fixed by the locking mechanism 63, and movement is restricted. In this state, after inserting the guide wire 100 in the other end side opening 36 through the side hole 51, priming liquid, such as a physiological saline, is poured in from the injection port 62, and priming of the inside of the catheter lumen 50 for extension is carried out. Since the stopper's 6 rear end part and the tip part of the sheath 5 touch, priming liquid has not leaked from a sheath tip. And the catheter 10 for living body organic extension is inserted into the abdominal cavity via a guiding catheter (not shown), and it derives to a target part along with the guide wire 100.

[0043]After the tip of the living body organic extension appliance implement 1 reaches near a target part, the branch hub 60 is held by one hand, the locking mechanism 63 is canceled, the catheter 10 for extension is extruded to the tip side to the sheath 5, and the stent 4 is exposed. After the stent 4 has been thoroughly exposed, as shown in drawing 12, the opening tip 36b of the other end side opening 36 is located in the end face close-attendants side at the tip of the side hole 51. Then, the stent 4 is extended and detained in a target part, and operation is ended. As mentioned above, although the living body organic extension appliance implement was explained, the composition of a living body organic extension appliance implement is not restricted to what was mentioned above.

[0044]

[Effect of the Invention]Folding and the extensible balloon in which the living body organic extension appliance implement of this invention was formed in the tube shape shaft body part and the tip part of this shaft body part, The stent which it is equipped with so that this balloon in the state where it was folded up may be wrapped entirely, and is extended by extension of this balloon, The catheter for extension provided with the guide wire lumen in which one end carries out an opening at the tip of said shaft body part, and the other end carries out an opening in the pars intermedia of said shaft body part, Are the sheath which has a catheter lumen which stores said catheter for extension slidably a living body organic extension appliance implement which it has, and said sheath, It has a side hole which extends in the shaft orientations for inserting in a guide wire in said guide wire lumen provided in the position used as near the other end side opening of said guide wire lumen of said

dilator implement, The side hole formation part of this sheath serves as a high rigidity part whose rigidity is higher than the tip part of said sheath. For this reason, there are few falls of the operativity which originates in absorption in the torque and the sheath side hole formation part of pressing force (if it puts in another way pusher kinky thread tee) which were given to the fracture [in a sheath side hole formation part] and rear end part side of a living body organic extension appliance implement in the living body extension appliance implement of this invention.

[Translation done.]

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TECHNICAL FIELD

[Field of the Invention]This invention relates to the living body organic extension appliance implement used for the improvement of the narrow segment formed in living body organs, such as an organ of a blood vessel, a bile duct, a trachea, an esophagus, an urethra, and others. It is related with the possible living body organic extension appliance implement of carrying especially the strangulation lesion in endovascular treatment, and the stent for living body organic extension mainly performed after the PTCA enforcement in strangulation parts, such as the heart and the blood vessels, to the purpose living body organic part to the basis of safety and smooth operativity.

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PRIOR ART

[Description of the Prior Art]The living body organic dilation which detains the stent in the narrow segment of living body lumina, such as an organ of a blood vessel, a bile duct, an esophagus, a trachea, an urethra, and others, or the abdominal cavity, and secures a lumen or abdominal cavity space conventionally is performed. As stent used for this, there are balloon expander bull stent and self expander bull stent by the function and the detention method. In order for expanded function not to have the balloon expander bull stent in the stent itself and to detain the stent in a target part, For example, after inserting the stent with which the expansion body (balloon) was equipped to a target part, make a balloon extend, make the stent extend with the extension power of a balloon (plastic deformation), and it is made to stick to the inner surface of a target part, and fixes. As a living body organic extension appliance implement detained in a target part, the balloon expander bull type stent, The stent feeding system which consists of a sheath which carries out dilation balloon catheter entire covering with the dilation balloon catheter which has an extended balloon which extends the stent to JP,H6-23507,A, and what is called a rapid exchange system are indicated. This stent feeding system has a guide wire lumen which carries out an opening in the tip and pars intermedia of a dilation balloon catheter, and the side hole formed in sheath pars intermedia.
A guide wire can be inserted in the opening formed in catheter pars intermedia through the side hole of a sheath from the middle of the sheath, and stent operation can be performed.

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EFFECT OF THE INVENTION

[Effect of the Invention]Folding and the extensible balloon in which the living body organic extension appliance implement of this invention was formed in the tube shape shaft body part and the tip part of this shaft body part, The stent which it is equipped with so that this balloon in the state where it was folded up may be wrapped entirely, and is extended by extension of this balloon, The catheter for extension provided with the guide wire lumen in which one end carries out an opening at the tip of said shaft body part, and the other end carries out an opening in the pars intermedia of said shaft body part, Are the sheath which has a catheter lumen which stores said catheter for extension slidably a living body organic extension appliance implement which it has, and said sheath, It has a side hole which extends in the shaft orientations for inserting in a guide wire in said guide wire lumen provided in the position used as near the other end side opening of said guide wire lumen of said dilator implement, The side hole formation part of this sheath serves as a high rigidity part whose rigidity is higher than the tip part of said sheath. For this reason, there are few falls of the operativity which originates in absorption in the torque and the sheath side hole formation part of pressing force (if it puts in another way pusher kinky thread tee) which were given to the fracture [in a sheath side hole formation part] and rear end part side of a living body organic extension appliance implement in the living body extension appliance implement of this invention.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]However, in the rapid exchange system of the above-mentioned composition, when a guide wire contacts a side hole by receipts-and-payments operation of a guide wire, there is a possibility that the circumference of a sheath side hole may fracture. Since the sheath side hole formation part is more nearly vulnerable than other portions, there is a possibility that the circumference of a side hole may produce a fracture. The torque and pressing force (if it puts in another way pusher kinky thread tee) which were given in the sheath side hole formation part at the rear end part side of a living body organic extension appliance implement during stent placement operation are absorbed, and there is a possibility of producing the fall of operativity. Then, this invention solves the above-mentioned problem.
The purpose is to provide a living body organic extension appliance implement with the fall of operativity, such as a fracture near a sheath opening, arising [little].

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MEANS

[Means for Solving the Problem]Folding and an extensible balloon in which what attains the above-mentioned purpose was provided in a tube shape shaft body part and a tip part of this shaft body part, Stent which it is equipped with so that this balloon in the state where it was folded up may be wrapped entirely, and is extended by extension of this balloon, It is a living body organic extension appliance implement provided with a catheter for extension provided with a guide wire lumen in which one end carries out an opening at the tip of said shaft body part, and the other end carries out an opening in pars intermedia of said shaft body part, and a sheath which has a catheter lumen which stores said catheter for extension slidably. And said sheath is provided with a side hole which extends in shaft orientations for inserting a guide wire in said guide wire lumen provided in a position used as near the other end side opening of said guide wire lumen of said catheter for extension, A side hole formation part of this sheath serves as a high rigidity part whose rigidity is higher than a tip part of said sheath.
[0005]Said catheter for extension is slidable to a state which the back end of said stent exposes in said sheath from a state where a tip of said stent of said catheter for extension was stored in said sheath, As for said side hole of said sheath, it is preferred equivalent to the length of said stent or to have shaft-orientations length beyond it. It is preferred to be produced with a resin material whose hardness is higher than a resin material which constitutes a tip part of said sheath from a tip part of said side hole formation part of said sheath to a base end of said sheath. As for a resin material with said high hardness, it is preferred that it is a with a Shore D hardness [of 55 or more] resin material. As for a resin material with said high hardness, it is preferred that they are polyester or polyamide. As for a tip part of said sheath, it is preferred to be produced with a with a Shore D hardness of 50 or less resin material. As for a resin material which constitutes a tip part of said sheath, it is preferred that they are polyester or polyamide.
[0006]As for said side hole formation part, it is preferred to have a metal reinforcing member. As for said reinforcing member, it is preferred that it is a tubular member which has two or more openings. As for said reinforcing member, it is preferred that it is a wire-like member. Said sheath consists of a sheath outer layer and a sheath inner layer formed inside this sheath outer layer, and, as for this sheath inner layer, being produced with fluororesin material is preferred. As for said inner layer, it is preferred to be produced so that it may project from said sheath outer layer tip. It is preferred to have a locking mechanism which fixes said catheter for extension in arbitrary positions to said sheath. As for said catheter for extension, it is more preferred than said stent to have a stopper which is formed in the tip side and prevents movement in the direction of a tip of said sheath.
[0007]
[Embodiment of the Invention]The living body organic extension appliance implement of this invention is explained using the preferred embodiment shown in Drawings. Drawing 1 the front view of one working example of the living body organic extension appliance implement of this invention and drawing 2, The expanded sectional view near the tip of the living body organic extension appliance implement shown in drawing 1 and drawing 3, The expanded sectional view of the central joining section of the living body organic extension appliance implement shown in drawing 1 and drawing 4, The A-A line sectional view of drawing 1 and drawing 5 the B-B line sectional view of drawing 1 and drawing 6, The C-C line sectional view of drawing 3 and drawing 7 the D-D line sectional view of drawing 3 and drawing 8, The expanded sectional view of the branch hub of the living body organic extension appliance implement shown in drawing 1 and drawing 9 are explanatory views for the expanded sectional view of the rear end part of the catheter for extension of the living body organic extension appliance implement shown in drawing 1 and drawing 10 to describe other working example of the living body organic extension appliance implement of this invention.
[0008]The living body organic extension appliance implement 1 of this invention The tube shape shaft body part 21, Folding and the extensible balloon 3 which were provided in the tip part of the shaft body part 21, The stent

4 which it is equipped with so that the balloon 3 in the state where it was folded up may be wrapped entirely, and is extended by extension of the balloon 3, It has the catheter 10 for extension provided with the guide wire lumen 15 in which one end carries out an opening at the tip of the shaft body part 21, and the other end carries out an opening in the pars intermedia of the shaft body part 21, and the sheath 5 which has the catheter lumen 50 which stores the catheter 10 for extension slidably. And the sheath 5 is provided with the side hole 51 which extends in the shaft orientations for inserting the guide wire 100 in the guide wire lumen 15 provided in the position used as near the other end side opening of the guide wire lumen 15 of the catheter 10 for extension, The side hole formation part 52b of the sheath serves as a high rigidity part whose rigidity is higher than the tip part 52a of the sheath 5.

[0009]The living body organic extension appliance implement 1 of this invention is what is called what is called a rapid exchange type, It has the guide wire lumen 15 which it was provided in catheter 10 inside for extension as shown in drawing 1 and drawing 3, and carried out the opening (other end side opening 36) in the tip and pars intermedia of the catheter 10 for extension, and the side hole 51 for guide wire insertion formed in sheath pars intermedia. By such composition, the living body organic extension appliance implement 1 can insert a guide wire in the opening (other end side opening 36) formed in catheter pars intermedia through the side hole of a sheath from the middle (pars intermedia) of the sheath, and can be performing stent operation.

[0010]As shown in drawing 1, the living body organic extension appliance implement 1 The shaft body part 21, The stopper 6 formed at shaft body part 21 tip, and the balloon 3 for stent extension provided in the tip part of the shaft body part 21, It consists of the catheter 10 for extension which consists of the stent 4 with which it was equipped on the balloon 3, and the hub 8 attached to the rear end part of the shaft body part 21, the sheath 5 which wraps the catheter 10 entirely, and the branch hub 60 attached to the rear end part of the sheath 5.

[0011]The catheter 10 for extension consists of the tip side shaft part 10a and the back end side shaft part 10b, and the tip side shaft part 10a and the back end side shaft part 10b are joined via the junction connector 7, as shown in drawing 1 and drawing 3. The catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes in the sheath 5 from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5. The inner tube 12 with which the tip side shaft part 10a forms the guide wire lumen 15 as shown in drawing 2 and drawing 3, It consists of the balloon 3 provided in the tip part of the inner tube 12, the stent 4 with which the periphery of the balloon 3 was equipped, and the outer tube 13 which is provided in the back end side from the balloon 3, wraps the inner tube 12 entirely, and forms the lumen 16 for balloon extension between the outside surfaces of the inner tube 12. And the tip side shaft part 10a is slidably stored in the catheter lumen 50 of the sheath 5. And the rear end part of the tip side shaft part 10b is joined to the tip part of the junction connector 7.

[0012]The balloon 3 has the tip side joined part 3a and the back end side joined part 3b, as shown in drawing 2. the tip side joined part 3a is fixed to the position by the side of the back end a little from the tip of the inner tube 12, and the back end side joined part 3b is being fixed at the tip of the outer tube 13. The balloon 3 is open for free passage with the lumen 16 for balloon extension near a base end. And the stopper 6 is being fixed at the tip of the inner tube 12 so that the tip part of the tip side joined part 3a of the balloon 3 may be wrapped entirely. The stopper 6 is annularly formed with the spring material, and his outer diameter of a rear end part is almost equal to the inside diameter of the sheath 5, or he is a little large. Thus, by having the stopper 6, movement in the direction of a tip of the stent 4 is prevented, and the stent 4 is not omitted from a catheter during stent placement operation. The stopper 6 is the tapered shape whose diameter is reduced gently-sloping toward a tip. By forming in this way, the derivation function to a narrow segment can be given to the stopper 6, and insertion to the narrow segment of a living body organ becomes easy about a stent mounting section.

[0013]And as the inner tube 12, an outer diameter is 0.45-0.8 mm preferably 0.35-1.0 mm, and an inside diameter is 0.35-0.7 mm preferably 0.2-0.9 mm. As the outer tube 13, an outer diameter is 0.8-1.1 mm preferably 0.6-1.5 mm, and an inside diameter is 0.7-1.0 mm preferably 0.5-1.4 mm. As the sheath 5, an outer diameter is 1.2-1.5 mm preferably 0.8-1.8 mm, and an inside diameter is 1.0-1.3 mm preferably 0.5-1.5 mm. As a formation material of the inner tube 12, the outer tube 13, and the stopper 6, What has a certain amount of flexibility is preferred, for example, thermoplastics, such as polyamide, polyester, polyolefine (bridge construction or a partial bridge construction thing is also included), polyvinyl chloride, and polyurethane, silicone rubber, latex rubber, etc. can be used, and it is the desirable above-mentioned thermoplastics.

[0014]The balloon 3 can be folded up and can be in the state where it was folded up by the periphery of the inner tube 12, in the state where it is not made to extend. The balloon 3 has the extensible part 31 which became a cylindrical section (preferably cylinder part) of the diameter of the same mostly so that the stent 4 with which it is equipped could be extended. The above-mentioned approximate circle pipe portion may not be a perfect cylinder, but may be a multiple pillar-like thing. and the balloon 3 -- above -- the tip side joined part 3a -- the inner tube 12 -- again -- the back end side joined part 3b -- the tip of the outer tube 13 -- adhesives or

thermal melting arrival -- liquid -- it has adhered densely. The balloon 3 forms the growth space 3c between the inner surface of the balloon 3, and the outside surface of the inner tube 12, as shown in drawing 2. This growth space is open for free passage with the lumen 16 for extension in that perimeter in the rear end part. Thus, since the back end of the balloon 3 is open for free passage with the lumen for extension which has comparatively large capacity, it is more sure than the lumen 16 for extension. [the fluid for extension into a balloon]

[0015]As a formation material of the balloon 3, what has a certain amount of flexibility is preferred, for example, thermoplastics, such as polyolefine, polyvinyl chloride, polyamide, polyurethane, polyester, and poly ant rain sulfide, silicone rubber, latex rubber, etc. can be used. It is preferred that it is the material which can be extended especially, and the balloon 3 has the preferred thing which has high intensity and extension power and by which biaxial extension was carried out. As a size of the balloon 3, the outer diameter of a cylinder part (extensible part 31) when extended is 2.5-4.0 mm preferably 1.5-5.0 mm, and length is 10-40 mm preferably 5-50 mm. The outer diameter of the tip side joined part 3a is 0.7-1.0 mm preferably 0.5-1.5 mm, and length is 1.0-1.3 mm preferably 1-5 mm. The outer diameter of the back end side joined part 3b is 1.0-1.5 mm preferably 0.8-1.6 mm, and length is 2-4 mm preferably 1-5 mm.

[0016]And the tip side imaging marker 17 is being fixed to the outside surface of the position which becomes the shaft body part 21 (this working example inner tube 12) with near the tip inside the extensible part 31 of the balloon 3. Similarly, the back end side imaging marker 18 is being fixed to the outside surface of the position which becomes the shaft body part 21 (this working example inner tube 12) with near the back end inside the extensible part 31 of the balloon 3. As for an imaging marker, it is preferred to form with radiopacity materials (for example, gold, platinum, tungsten, those alloys, or a silver-palladium alloy etc.). The position of the position of the tip of the extensible part 31 of the balloon 3 and the back end and by extension, the tip of the stent 4, and the back end can be checked by X ray imaging by doing in this way.

[0017]The stent 4 used for the living body organic extension appliance implement 1 of this invention, If it puts in another way when the power which is formed in an abbreviated tubular body, has a diameter for insertion to the living body, and spreads in the method of the outside of a radial direction from the inside of a tubular body is added, when the balloon 3 is extended, it will be extensible (extension is possible), and will be what is called balloon expander bull stent. As the stent 4, as shown in drawing 14, the component 22 of the shape of an approximately ellipse to which the center section was annoyed by the shaft orientations of the stent 4 for a long time, or polygonal shape, for example, it being mostly arranged on an approximate circle circumference in an equiangular distance to the medial axis of the stent 4, and. Between the adjoining parts (flank) of the circumferencial direction of a component consists of the annular unit 24 (24a, 24b, 24c, 24d, 24e, 24f) connected in the terminal area 23 (23a, 23b, 23c, 23d), And two or more annular units 24a, 24b, 24c, 24d, 24e, and 24f are located in a line with the shaft orientations of the stent 4. What at least one terminal area 23 of the annular unit 24 which adjoins the terminal area 23 of the one annular unit 4 is connected to by the connecting part 25 (25a, 25b, 25c, 25d, 25e) is preferred. However, the shape of the stent 4 is not limited to such a thing, and can use publicly known things, such as mesh shape.

[0018]What has a certain amount of biocompatibility as a formation material of the stent 4 is preferred, for example, stainless steel, tantalum or a tantalum alloy, and the platina ****** can consider a platinum alloy, gold or a gold alloy, a cobalt base alloy, etc. After producing stent shape, noble metal plating (gold, platina) may be carried out. As stainless steel, SUS316L which has corrosion resistance most is preferred. About 0.8-1.5 mm is preferred for the diameter at the time of un-extending of the stent 4, and its 0.9-1.2 mm is especially more preferred.

[0019]The back end side shaft part 10b consists of the shaft tube 32 and the hub 8 fixed to the back end of the shaft tube 32, as shown in drawing 1 and drawing 3. And the back end side shaft part 10b is slidably stored in the catheter lumen 50 of the sheath 5. And the tip part of the back end side shaft part 10b is joined to the rear end part of the junction connector 7. Into the shaft tube 32, as shown in drawing 1 and drawing 7, the rigid grant object 33 is inserted, and the rigid grant object 33 is fixed to the shaft tube 32 in a rear end part, and a tip, From the tip of the shaft tube 32, it projected, the junction connector 7 mentioned later was penetrated, and it has extended in the tip side shaft. In other words, in this working example, the tip part of the rigid grant object 33 has reached in the lumen 16 for balloon extension between the inner tube 12 of a tip side shaft, and the outer tube 13.

[0020]The rigid grant object 33 is prolonged in the tip side in the inside from the end face of the shaft tube 32. The rigid grant object 33 is being fixed to the shaft tube 32 or the hub 8 by only the base end, and so that it may not become an obstacle of a curve of the shaft body part 21 on other portions and a concrete target. It is being fixed to neither the inside except the base end of the shaft tube 32 nor junction connector 7 portion nor the tip side shaft part (the inner tube 12 and the outer tube 13). The rigid grant object 33 prevents meandering within

that the degree of pole of the shaft tube 32 in a crookedness part bends, and the blood vessel of the shaft tube 32, without reducing the flexibility of the shaft tube 32 not much. As for the rigid grant object 33, being formed with the line object is preferred. As a line object, it is desirable, and it is elastic metal, such as 0.1-1.0-mm stainless steel, a superelastic alloy, etc. preferably that it is a metal wire, and 0.05-1.5 mm of wire sizes are the high tension stainless steel for springs, and a superelastic alloy line especially preferably.

[0021]Generally a superelastic alloy here is called shape memory alloy, and shows superelasticity at living body temperature (near 37 **) at least. Superelastic alloys, such as Ti-Ni alloy of 49 -53-atom %nickel, Cu-Zn alloy of 38.5 to 41.5-% of the weight Zn, a Cu-Zn-X alloy (X=Be, Si, Sn, aluminum, Ga) of 1-10 % of the weight X, and nickel-aluminum alloy of 36 to 38 atom %aluminum, are used especially suitably preferably. Especially, the above-mentioned Ti-Ni alloy is desirable. . [whether some Ti-Ni alloys are used as the Ti-nickel-X alloys (X=Co, Fe, Mn, Cr, V, aluminum, Nb, W, B, etc.) replaced by 0.01-10.0 atom %X, and] Or a mechanical property is changeable suitably by choosing the conditions of using some Ti-Ni alloys as the Ti-nickel-X alloy (X=Cu, Pb, Zr) replaced by 0.01-30.0 atom %X and a cold working rate, or/and final heat treatment. A mechanical property is changeable suitably by choosing the conditions of a cold working rate and/or final heat treatment using the above-mentioned Ti-nickel-X alloy.

[0022]The shaft tube 32 is fixing the rigid grant object 33 in a end face, and the back end of this shaft tube 32 is being further fixed to the tip part of the hub 8. The tube 35 for kink prevention is attached to the outside surface of the boundary part of the hub 8 and the shaft tube 32 so that both may be covered. The rear end part of the hub 8 is the terminal area 34 of the fluid transfer pipet implement for balloon extension (for example, syringe). As the shaft tube 32, an outer diameter is 0.6-1.3 mm preferably 0.5-1.5 mm, and an inside diameter is 0.5-1.2 mm preferably 0.3-1.4 mm. What has a certain amount of flexibility as a formation material of the shaft tube 32 is preferred, for example, polyolefine (for example, polyethylene and polypropylene.) Ethylene propylene rubber, an ethylene-vinylacetate copolymer, etc. can use thermoplastics, such as polyvinyl chloride, a polyamide elastomer, polyimide, and polyurethane, silicone rubber, latex rubber, etc., and it is the desirable above-mentioned thermoplastics. A stainless steel tube may be used as a formation material of the shaft tube 32, without using the rigid grant object 33.

[0023]The junction connector 7 is prolonged from a tip center in shaft orientations to a center section, as shown in drawing 3. It has an inner-tube insertion passage which curves from a center section and arrives at the lateral surface by the side of the back end, the rear end part of the inner tube 12 penetrates the inside of this insertion passage, and the rear end part of the inner tube 12 which projects from the side of the junction connector 7 forms guide wire introduction RO 36 (other end side opening 36). The opening of the other end side opening 36 is formed toward the end face side slanting upper part of drawing 3. Direction of an opening may not be restricted to the thing of working example, but may be formed toward right above drawing 3. The fluid distribution ways 37a and 37b for balloon extension which extend in a end face from a tip are formed in the junction connector 7. By this circulation way, the lumen 16 for balloon extension currently formed of between the inner tube 12 and the outer tubes 13 and the lumen 16 for balloon extension currently formed in the shaft tube 32 are open for free passage. The rigid grant object conduction passage penetrated to the end face is formed in the junction connector 7 from the tip as mentioned above, and the rigid grant object 33 has penetrated this.

[0024]The sheath 5 is provided with the following.

As shown in drawing 1, drawing 2, and drawing 3, it is produced by tube shape, and it is the catheter lumen 50 to an inside.

It is the side hole 51 to pars intermedia.

Where the tip of the stent 4 is stored in the catheter lumen 50, the tip part of the stent 4 and the stopper's 6 back end touch mostly. The rear end part of the sheath 5 is joined to the tip part of the branch hub 60. The catheter lumen 50 serves as a passage which stores the catheter 10 for extension slidably as shown in drawing 1 and drawing 3. In other words, the catheter lumen 50 is a passage which enables insertion of the catheter 10 for extension, The tip of the catheter 10 for extension was projected from the tip of the catheter lumen, i.e., the tip of a sheath, and the base end of the catheter 10 for extension is projected from the back end of the catheter lumen, i.e., the back end of a sheath.

[0025]The side hole 51 is formed in order to insert in the guide wire 100 in the guide wire lumen 15. The guide wire 100 is inserted in the other end side opening 36 via the side hole 51, and is introduced in the guide wire lumen 15. The side hole 51 is produced as an ellipse-like opening prolonged in shaft orientations, as shown in drawing 1 and drawing 3, and it is formed so that it may be open for free passage with the catheter lumen 50 in the position used as the other end side opening 36 neighborhood which is a guide wire loading slot of the guide wire lumen 15.

[0026]The catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes in the sheath 5 from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5,

The side hole 51 of the sheath 5 is equivalent to the length of the stent 4, or is provided with the shaft-orientations length beyond it. Thus, when the side hole 51 has a certain amount of length in shaft orientations, exposure of the other end side opening 36 (guide wire loading slot) is completely attained out of a sheath in the back end of the stent 4 in the state where it was located in the side hole 51. In the state where the tip of the stent 4 was specifically stored in the sheath as shown in drawing 11, The end face 36a of the other end side opening 36 is located in the tip side from the end face of the side hole 51, and the end face 36a of the other end side opening 36 is located in the end face side from the tip of the side hole 51 in the state where the stent 4 was thoroughly exposed from sheath 5 tip as shown in drawing 12. In this state, it is preferred to be constituted so that the tip 36b of the other end side opening 36 may also be located in the end face side from the tip of the side hole 51. For this reason, since the guide wire 100 cannot contact easily during stent placement operation in the side hole 51, it is hard to damage a side hole formation part.

[0027]At the time of insertion in the living body, the living body organic extension appliance implement 1, In [are in the state where most stopper 6 portions of the catheter for extension are exposed, and the stent 4 is not exposed at all from the tip of the sheath 5 as shown in drawing 1, and] this state, The catheter 10 for extension is being fixed by the catheter locking mechanism 63 of the branch hub 60 established in the rear end part of the sheath 5 mentioned later. For this reason, unless the catheter locking mechanism 63 is canceled, the state of drawing 1 is maintained, and the inside of a sheath cannot be slid on the catheter for extension. In the state where it is not locked by the catheter locking mechanism 63 in the sheath 5, the catheter 10 for extension is slidable to the state which the back end of the stent 4 exposes from the state where the tip of the stent 4 of the catheter 10 for extension was stored in the sheath 5.

[0028]The sheath 5 is formed from the sheath outer layer 52 and the sheath inner layer 53 formed inside the sheath outer layer 52, as shown in drawing 1 – drawing 3, drawing 10 – drawing 12. The sheath outer layer 52 and the sheath inner layer 53 are unified. And as shown in drawing 1 and drawing 2, the tip of the sheath outer layer 52 and the tip of the sheath inner layer 53 are produced so that it may become the almost same position as the shaft orientations of a sheath. As shown in drawing 8, the end face of the sheath outer layer 52 and the sheath inner layer 53 is joined to the tip part of the branch hub 60 by adhesives, thermal melting arrival, etc. Although produced as a two-layer structure of an outer layer and a inner layer in working example, it may be the multilayer structure of three or more layers. A sheath may be layer structure.

[0029]As for the sheath inner layer 53, being formed with fluororesin material is preferred. As a fluororesin material, polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), etc. can be used and it is polytetrafluoroethylene preferably. By producing a sheath inner layer with fluororesin material, it becomes easy to slide on a catheter lumen wall, and the catheter for extension slides easily in a catheter lumen. As for the sheath outer layer 52, it is preferred to be produced with the resin which has flexibility to some extent so that the bent lumen in the living body can be gone on easily. As a component of the sheath outer layer 52, thermoplastics, such as polyamide, polyester, polyolefine (bridge construction or a partial bridge construction thing is also included), polyvinyl chloride, and polyurethane, etc. can be used, and it is the desirable above-mentioned thermoplastics, for example.

[0030]The side hole formation part (side hole surrounding portion) of the sheath 5 serves as a high rigidity part whose rigidity is higher than the tip part of the sheath 5. It is hard to produce the fall of the operativity by absorption of the torque and pressing force (if it puts in another way pusher kinky thread tee) which were given to the rear end part side of the living body organic extension appliance implement in a side hole formation part, such as a fracture of a side hole formation part, by constituting in this way that it is [under / stent placement operation / setting]. It is produced with the resin material whose hardness is specifically higher than the resin material which constitutes the tip part 52a of the sheath 5 (sheath outer layer 52) from the tip part of the side hole formation part 52b of the sheath 5 (sheath outer layer 52) to the base end 52c of the sheath 5 (sheath outer layer 52).

[0031]As for the resin material with high hardness, it is preferred that it is a with a Shore D hardness [of 50 or more] resin material, and it is especially preferred that it is the Shore D hardness of 55 or more. As for the resin material with high hardness, it is preferred that they are polyester and polyamide. As polyester system resin, polyethylene terephthalate, polybutylene terephthalate, etc. are preferred and polyethylene terephthalate preferably. As polyamide system resin, nylon 6, Nylon 66, Nylon 46, Nylon 11, Nylon 12, etc. are preferred. As for the tip part 52a of a sheath, it is preferred to be produced with a with a Shore D hardness of 50 or less resin material. Thereby, the tip part of a sheath becomes what has pliability, and can advance the complicated living body lumen smoothly. The resin material which constitutes the sheath tip part 52a, a polyester elastomer and an olefin system elastomer (for example, a polyethylene elastomer.) A polypropylene elastomer, a polyamide elastomer, a styrene system elastomer. for example, styrene butadiene styrene copolymer and styrene isoprene styrene copolymer. Flexible resin, such as styrene ethylene butylene styrene copolymer, a polyamide elastomer,

a polyester elastomer, and a thermoplastic fluorinated elastomer, is preferred.
[0032]The sheath tip part 52a the sheath 5, for example by a with a Shore D hardness of 50 or less polyamide elastomer. and the side hole circumference 52b — a with a Shore D hardness [of 50 or more] polyamide elastomer -- and the sheath base end 52c can produce by a with a Shore D hardness [of 50 or more] polyamide elastomer. Even if a guide wire is inserted in the other end opening 36 through the side hole 51 and it performs stent placement operation by constituting a sheath as mentioned above, The side hole formation part 52b does not have a possibility of producing the fall of the operativity resulting from the torque and pressing force (if it puts in another way pusher kinky thread tee) which were given to the rear end part side of a living body organic extension appliance implement being absorbed by the side hole formation part 52b, without fracturing. In working example, after producing the tip part 52a of the sheath 5, the side hole formation part 52b of the sheath 5, and the base end 52c of the sheath 5 as respectively different component part, join and unify, and are producing the sheath, but. Not the thing restricted to this but the side hole formation part 52b and the base end 52c are produced as one component part, it may join to the tip part 52a, and a sheath may be produced. Thermal melting arrival, adhesives, etc. can perform junction.
[0033]As for the outside surface of the sheath tip part 52a, it is preferred that hydrophilization treatment is performed. As hydrophilization treatment, it can carry out by coating a sheath outside surface with hydrophilic substances (for example, water-soluble silicone, PVA, PVP, etc.). As a size of a sheath, 1.2-1.5 mm and an inside diameter are [1.0-1.3 mm and the length of an outer diameter] 1200-1400 mm 800-1600 mm 0.8-1.5 mm preferably 0.8-1.8 mm. As a size of the side hole 51 of a sheath, the lay length to which the shaft orientations of 15-50 mm and a sheath and the length of the shaft orientations of a sheath cross at right angles preferably 5-80 mm is 0.35-0.7 mm preferably 0.1-1.0 mm.
[0034]The side hole formation part 52b of the sheath 5 may have the metal reinforcing member 54 like the living body organic extension appliance implement of working example shown in drawing 10. Absorption of the torque in the fracture of the sheath side hole 51 circumference and a side hole formation part, etc. can be prevented by providing a metal reinforcement member in a side hole formation part. As for the metal reinforcing members 54, it is preferred that it is a tubular member which has two or more openings 541 as shown in drawing 13. The metal reinforcement member is mostly produced as a tubular member of the diameter of the same, and has the opening 541 elliptical [two or more] prolonged along the shaft orientations of a tubular member. As an opening configuration, it may not be restricted to elliptical, but may be rectangular form etc. The tubular member is installed so that one opening may lap with the side hole 51 among two or more openings of a tubular member, while contacting the inner layer 53 at the sheath outer layer wall of the side hole formation part 52b. As how to embed a tubular member, the outer layer by the side of a end face is formed at portions other than a tip end part on that with which the inner layer formation material was covered on the surface of rodding, It can carry out by inserting in and attaching a tubular member on the base end of an outer layer agenesis portion, covering resin for side hole formation parts on it, and producing further by covering resin for tip part formation parts on the tip part of an outer layer agenesis portion.
[0035]It may be produced by the wire-like member although not illustrated as a metal reinforcement member. In the case of a wire-like member, it is preferred to embed two or more linear shape wires along the shaft orientations of a sheath at the sheath wallplate of the circumference 52b of a side hole. A wire-like member may be produced a coiled form or in the shape of a braid, and it may also be embedded at the sheath wall of the side hole 51 neighborhood. Metal reinforcing members may be formed combining a linear shape wire and a coiled wire. It is preferred to use the same material as the rigid grant object 33 as a component of a metal reinforcement member. As a size of the metal reinforcing members of a tubular member, length is 20-60 mm preferably 10-90 mm, an inside diameter is 1.1-1.4 mm preferably 0.9-1.6 mm, and the thickness of a wallplate is 0.05-0.10 mm preferably 0.03-0.15 mm. As a wire size of the metal reinforcement member of a wire-like member, it is 0.03-0.15 mm and is 0.05-0.10 mm preferably.
[0036]As for a sheath outside surface, it is preferred that hydrophilization treatment is performed. By this, when a sheath moves a living body lumen or the abdominal cavity, a wall is made damage, and it is a stake. As hydrophilization treatment, it can carry out by coating a sheath outside surface with hydrophilic substances (for example, water-soluble silicone, PVA, PVP, etc.). Like the living body organic extension appliance implement 70 of working example shown in drawing 15, the sheath 5 may be produced so that the sheath inner layer 73 may project in the tip side from the sheath outer layer 72. Thus, while being able to make thickness of a sheath thin by producing so that it may project in the tip side, the outer diameter of the tip part of a sheath can be made into a byway. It is preferred to be produced with fluororesin as such a sheath inner layer 73, as mentioned above. It is preferred that hydrophilization treatment is carried out to the outside surface of the projection part of a sheath inner layer. The length for the tip projection of the sheath inner layer 73 is 10-40 mm preferably 0.5-50 mm. Except for near a side hole formation part, it may produce with fluororesin among the inner layers 73 of a

sheath.
[0037]Next, the branch hub 60 is explained using drawing 8. The injection port 62 for priming provided so that it might branch from the body part 61 in the branch hub body part 61 and the center section of the branch hub body part 61 as the branch hub 60 was shown in drawing 8, It consists of the catheter locking mechanism 63 which is provided in the rear end part of the branch hub 60, and restricts movement of the catheter for extension, and the catheter lumen 64 for extension provided from the tip of a branch hub to the end face. The diameter of a catheter lumen of the back end 65 of the branch hub 60 is produced smaller than the tip part of the hub 8, and the tip part of the hub 8 is not moving at the tip from near the back end of the branch hub 60. The sheath rear end part is joined to the tip part of the branch hub 60. As for the rear end part of the sheath 5, it is preferred to be fixed to the end face side by the 1-5-mm position from the tip part of the branch hub 60.
[0038]The locking mechanism 63 consists of the elastic body 631 which pinches the base end of the catheter 10 for extension by compression, and the operation body 632 which compresses the elastic body 631. By having the locking mechanism 63, the catheter 10 for extension is fixed in arbitrary positions to the sheath 5. The elastic body 631 is installed in the crevice 611 established in the base end of the branch hub body part 61, and the lumen 631a which forms a part of catheter lumen 64 is formed in the inside of the elastic body 631. The inside diameter of the body part crevice 611 is produced somewhat more greatly than elastic body 631 outer diameter, and enables diameter expansion to the radial direction of the elastic body at the time of the elastic body 631 being compressed by the operation body 632. The lumen 631a of the elastic body 631 is produced by the shape where a part of two approximate sphere shape overlapped shaft orientations, and both ends and a center section are reducing the diameter of it. As long as the lumen 631a is not restricted to the shape of working example mentioned above and locks the catheter for extension exactly, it may be what kind of shape.
[0039]The operation body 632 is formed in the elastic body pressing part 632a projected to the tip side in the center section, and its periphery, and consists of the rear end part 611a of the crevice 611, the screwing part 632b to screw, and the support part 632c for supporting, when it is formed in the periphery of the screwing part 632c and the operation body 632 is rotated. The lumen 632d which forms a part of catheter lumen 64 is formed in the inside of the elastic body pressing part 632a. The tip side portion of the elastic body pressing part 632a is stored in the body part crevice 611, as shown in drawing 8, and it has compressed the elastic body 631 by movement at the tip of an operation body. When the operation body 632 is rotated and it screws in the tip side to the branch hub 60 by the above composition, the tip of the elastic body pressing part 632a contacts the back end of the elastic body 631, and the elastic body 631 is further compressed by shaft orientations by screwing the operation body 632 in the tip side. And a lumen 631a inside diameter becomes small, and the base end of the catheter 10 for extension is eventually fixed with the elastic body 631 as it compresses. Release of the locking mechanism 63 is performed by rotatably operating contrary to the above.
[0040]As a component of the branch hub 60 except the elastic body 631, polycarbonate, polyolefine (for example, polyethylene, polypropylene, ethylene-propylene copolymer), and styrene resin [-- for example, Polystyrene, MS resin (methacrylate styrene copolymer), and MBS resin (methacrylate butylene-styrene copolymer)], polyester, etc. can be used. As a component of the elastic body 631, urethane rubber, silicone rubber, Crude rubber, such as synthetic rubbers, such as butadiene rubber, and latex rubber, an olefin system elastomer. (For example, a polyethylene elastomer, a polypropylene elastomer), a polyamide elastomer and a styrene system elastomer (for example, styrene butadiene styrene copolymer.) Styrene isoprene styrene copolymer, styrene ethylene butylene styrene copolymer, polyurethane, a urethane system elastomer, a fluoro-resin system elastomer, etc. are preferred.
[0041]In working example of this invention, the sheath 5 is not restricted to this, although directly fixed to the tip part of the branch hub 60, it may attach a hub to sheath 5 rear end part, and may join a branch hub to a sheath by screwing it with the tip part of the branch hub 60. Where the stent 4 is stored in a sheath (state which lengthened the catheter 10 to the end face side), the rear end part of the branch hub 60 is being preferably fixed in a 50-100-mm position 10-200 mm from the tip part of the tube 35 for kink prevention.
[0042]Next, an operation of the living body organic extension appliance implement of this invention is explained. As shown in drawing 11, where stent 4 tip is stored in the sheath 5, the opening end face 36a of the other end side opening 36 is located in the tip close-attendants side of side hole 51 end face. And the catheter 10 for extension is fixed by the locking mechanism 63, and movement is restricted. In this state, after inserting the guide wire 100 in the other end side opening 36 through the side hole 51, priming liquid, such as a physiological saline, is poured in from the injection port 62, and priming of the inside of the catheter lumen 50 for extension is carried out. Since the stopper's 6 rear end part and the tip part of the sheath 5 touch, priming liquid has not leaked from a sheath tip. And the catheter 10 for living body organic extension is inserted into the abdominal cavity via a guiding catheter (not shown), and it derives to a target part along with the guide wire 100.
[0043]After the tip of the living body organic extension appliance implement 1 reaches near a target part, the

branch hub 60 is held by one hand, the locking mechanism 63 is canceled, the catheter 10 for extension is extruded to the tip side to the sheath 5, and the stent 4 is exposed. After the stent 4 has been thoroughly exposed, as shown in drawing 12, the opening tip 36b of the other end side opening 36 is located in the end face close-attendants side at the tip of the side hole 51. Then, the stent 4 is extended and detained in a target part, and operation is ended. As mentioned above, although the living body organic extension appliance implement was explained, the composition of a living body organic extension appliance implement is not restricted to what was mentioned above.

[Translation done.]

* NOTICES *

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]Drawing 1 is a front view of one working example of the living body organic extension appliance implement of this invention.
[Drawing 2]Drawing 2 is an expanded sectional view near the tip of the living body organic extension appliance implement shown in drawing 1.
[Drawing 3]Drawing 3 is an expanded sectional view of the central joining section of the living body organic extension appliance implement shown in drawing 1.
[Drawing 4]Drawing 4 is an A-A line sectional view of drawing 1.
[Drawing 5]Drawing 5 is a B-B line sectional view of drawing 1.
[Drawing 6]Drawing 6 is a C-C line sectional view of drawing 3.
[Drawing 7]Drawing 7 is a D-D line sectional view of drawing 3.
[Drawing 8]Drawing 8 is an expanded sectional view of the branch hub of the living body organic extension appliance implement shown in drawing 1.
[Drawing 9]Drawing 9 is an expanded sectional view of the rear end part of the expansive catheter of the living body organic extension appliance implement shown in drawing 1.
[Drawing 10]Drawing 10 is an explanatory view for describing other working example of the living body organic extension appliance implement of this invention.
[Drawing 11]Drawing 11 is an explanatory view for describing working example of the living body organic extension appliance implement of this invention.
[Drawing 12]Drawing 12 is an explanatory view for describing working example of the living body organic extension appliance implement of this invention.
[Drawing 13]Drawing 13 is a perspective view of working example of the reinforcing member installed in the circumference of a sheath side hole.
[Drawing 14]Drawing 14 is a perspective view showing working example of the stent used for the living body organic extension appliance implement of this invention.
[Drawing 15]Drawing 15 is an explanatory view for describing other working example of the living body organic extension appliance implement of this invention.
[Description of Notations]
1 Living body organic extension appliance implement
3 Balloon
4 Stent
5 Sheath
6 Stopper
7 Joined part
8 Hub
10 The catheter for extension
10a Tip side shaft part
10b Back end side shaft part
15 Guide wire lumen
21 Shaft body part
50 Catheter lumen
52 Outer layer
52b Side hole formation part
53 Inner layer
54 Metal reinforcement member

60 Branch hub

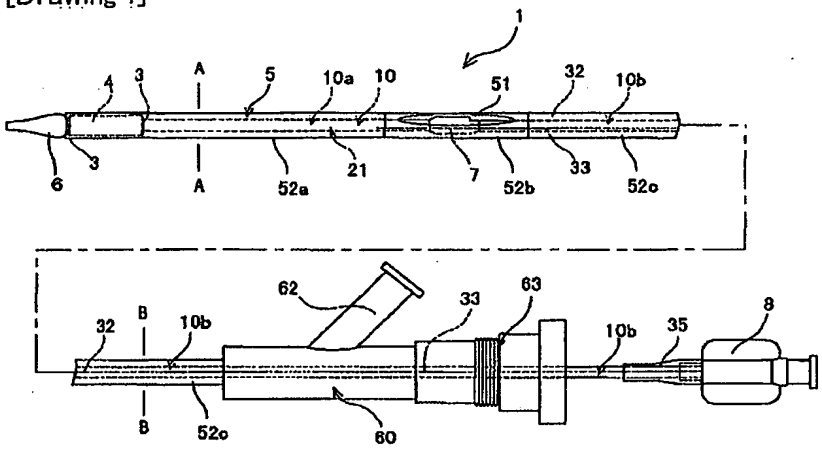
[Translation done.]

* NOTICES *

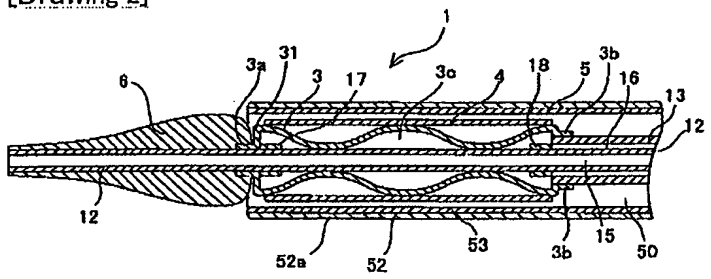
1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DRAWINGS

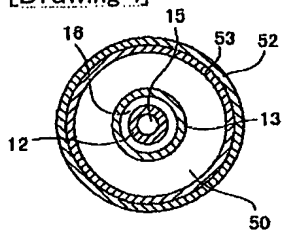
[Drawing 1]



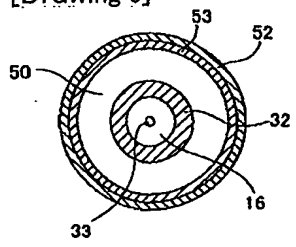
[Drawing 2]



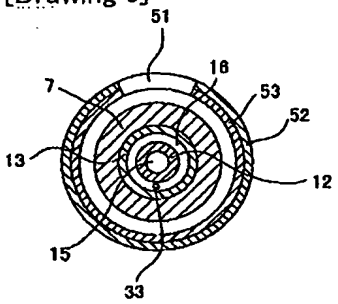
[Drawing 4]



[Drawing 5]



[Drawing 6]



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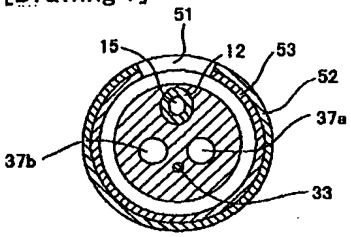

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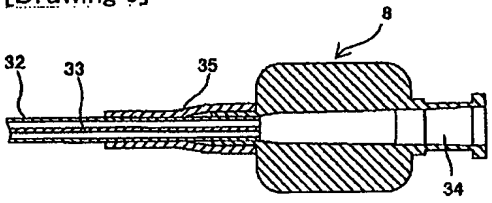

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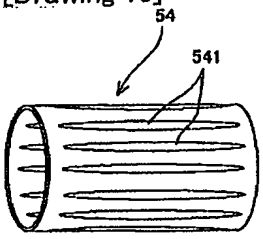

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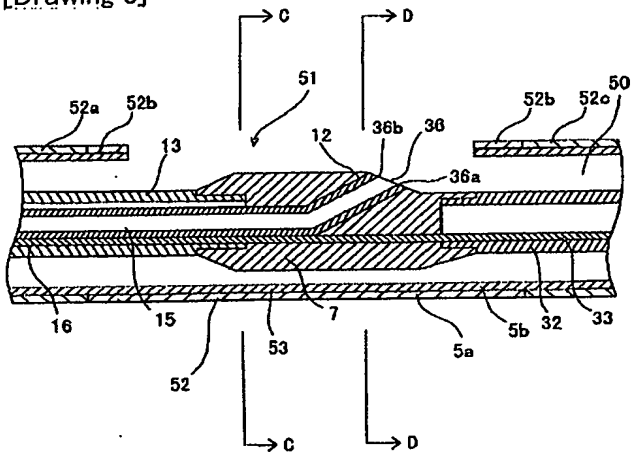

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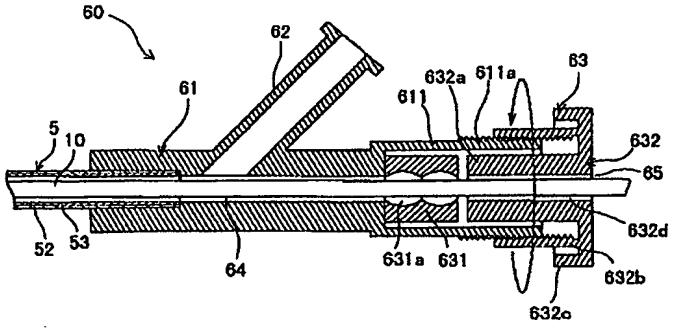

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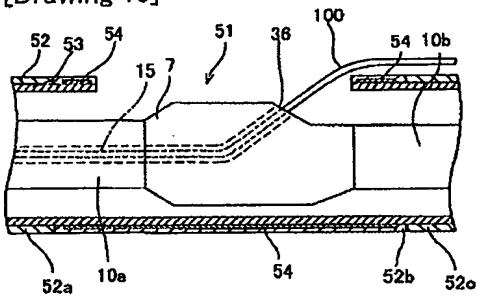

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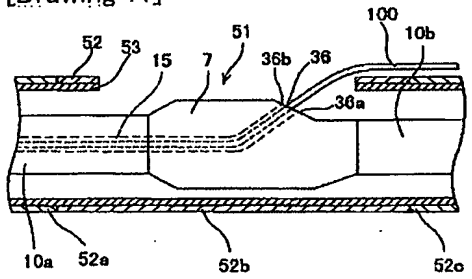

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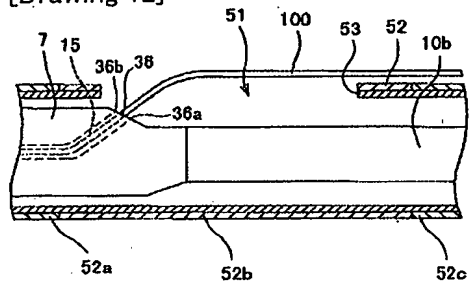

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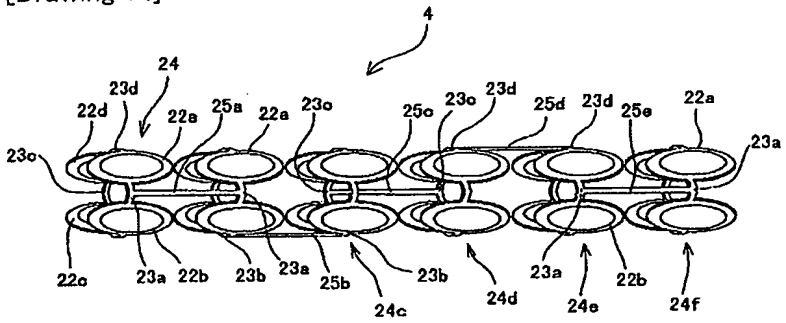

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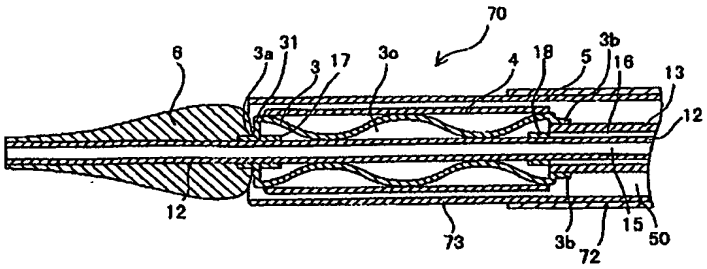

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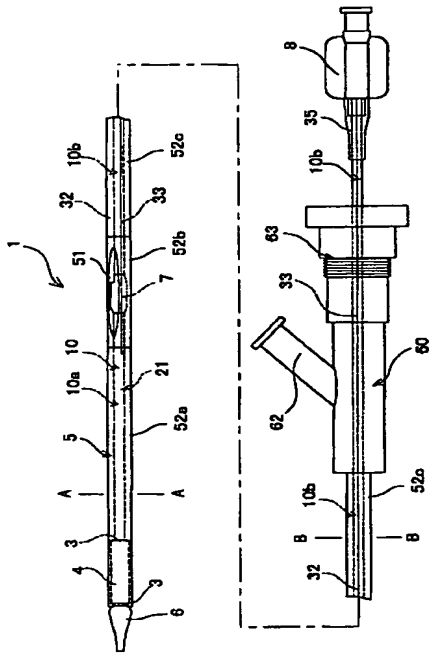
(54)【発明の名称】　生体器官拡張用器具

(57)【要約】
【課題】　シース開口部周囲の破断等もしくは操作性の低下が生じることのない生体器官拡張用器具を提供する。
【解決手段】　生体器官拡張用器具１は、シャフト本体部２１と、拡張バルーン３と、ステント４と、シャフト本体部２１の先端にて一端が開口し、他端がシャフト本体部２１の中間部にて開口するガイドワイヤールーメン１５を備える拡張用カテーテル１０と、チューブ状に作製されカテーテルルーメン５０と、ガイドワイヤーを挿通するための側孔５１を有しているシース５とからなるものであって、シース５の側孔形成部位５２ｂがシース５の先端部５２ａより高剛性となるように作製されている。



【特許請求の範囲】

【請求項１】　チューブ状のシャフト本体部と、該シャフト本体部の先端部に設けられた折り畳みおよび拡張可能なバルーンと、折り畳まれた状態の該バルーンを被包するように装着され、かつ該バルーンの拡張により拡張されるステントと、前記シャフト本体部の先端にて一端が開口し、他端が前記シャフト本体部の中間部にて開口するガイドワイヤールーメンとを備える拡張用カテーテルと、前記拡張用カテーテルを摺動可能に収納するカテーテルルーメンを有するシースとを備える生体器官拡張用器具であって、前記シースは、前記拡張用カテーテルの前記ガイドワイヤールーメンの他端側開口部付近となる位置に設けられた前記ガイドワイヤールーメンにガイドワイヤーを挿通するための軸方向に延びる側孔を備え、さらに、該シースの側孔形成部位は、剛性が前記シースの先端部より高い高剛性部となっていることを特徴とする生体器官拡張用器具。

【請求項２】　前記拡張用カテーテルは、前記シース内において、前記拡張用カテーテルの前記ステントの先端が前記シース内に収納された状態から前記ステントの後端が露出する状態まで摺動可能であり、前記シースの前記側孔は、前記ステントの長さと同等もしくはそれ以上の軸方向長さを備えている請求項１に記載の生体器官拡張用器具。

【請求項３】　前記シースの前記側孔形成部位の先端部から前記シースの基端部まで前記シースの先端部を構成する樹脂材料より硬度の高い樹脂材料により作製されている請求項１または２に記載の生体器官拡張用器具。

【請求項４】　前記硬度の高い樹脂材料は、ショアＤ硬度５５以上の樹脂材料である請求項３に記載の生体器官拡張用器具。

【請求項５】　前記硬度の高い樹脂材料は、ポリエステルまたはポリアミドである請求項３または４に記載の生体器官拡張用器具。

【請求項６】　前記シースの先端部は、ショアＤ硬度５０以下の樹脂材料により作製されている請求項１ないし５のいずれかに記載の生体器官拡張用器具。

【請求項７】　前記シースの先端部を構成する樹脂材料はポリエステルまたはポリアミドである請求項１ないし６のいずれかに記載の生体器官拡張用器具。

【請求項８】　前記側孔形成部位は、金属製補強部材を有している請求項１ないし７のいずれかに記載の生体器官拡張用器具。

【請求項９】　前記補強部材は、複数の開口を有する管状部材である請求項８に記載の生体器官拡張用器具。

【請求項１０】　前記補強部材は、ワイヤー状部材である請求項８に記載の生体器官拡張用器具。

【請求項１１】　前記シースは、シース外層と該シース外層の内側に形成されたシース内層とからなり、該シース内層は、フッ素系樹脂材料により作製されている１ないし１０のいずれかに記載の生体器官拡張用器具。

【請求項１２】　前記内層は、前記シース外層先端より突出するように作製されている請求項１１に記載の生体器官拡張用器具。

【請求項１３】　前記シースに対して前記拡張用カテーテルを任意の位置で固定するロック機構を備えている請求項１ないし１２のいずれかに記載の生体器官拡張用器具。

【請求項１４】　前記拡張用カテーテルは、前記ステントよりも先端側に設けられ、前記シースの先端方向への移動を阻止するストッパーを備える請求項１ないし１３のいずれかに記載の生体器官拡張用器具。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】本発明は、血管、胆管、気管、食道、尿道、その他の臓器などの生体器官内に形成された狭窄部の改善に使用される生体器官拡張用器具に関する。特に、血管内治療における狭窄病変、主に心血管等の狭窄部位におけるＰＴＣＡ施行後に行う生体器官拡張用ステントを安全かつ、スムーズな操作性のもとに、目的生体器官部位まで運ぶことの可能な生体器官拡張用器具に関するものである。

【０００２】

【従来の技術】従来より、血管、胆管、食道、気管、尿道、その他の臓器などの生体管腔または体腔の狭窄部にステントを留置して管腔または体腔空間を確保する生体器官拡張法が行われている。これに使用されるステントとしては、機能および留置方法によって、バルーンエキスパンダブルステントとセルフエキスパンダブルステントとがある。バルーンエキスパンダブルステントは、ステント自身に拡張機能はなく、ステントを目的部位に留置するには、例えば、拡張体（バルーン）に装着されたステントを目的部位まで挿入した後、バルーンを拡張させ、バルーンの拡張力によりステントを拡張（塑性変形）させ目的部位の内面に密着させて固定する。バルーンエクスパンダブルタイプのステントを目的部位へ留置する生体器官拡張用器具としては、特開平６－２３５０７号公報にステントを拡張する拡張バルーンを有する拡張バルーンカテーテルと拡張バルーンカテーテル被包するシースとからなるステント送入システム、いわゆるラピッドエクスチェンジシステムが開示されている。このステント送入システムは、拡張バルーンカテーテルの先端と中間部において開口するガイドワイヤールーメンと、シース中間部に形成された側孔を有しており、シースの途中からシースの側孔を通じてカテーテル中間部に形成された開口にガイドワイヤーを挿入して、ステント操作を行うことができるものとなっている。

【０００３】

【発明が解決しようとする課題】しかし、上記構成のラピッドエクスチェンジシステムにおいては、ガイドワイ

ヤーの出し入れ操作によりガイドワイヤーが側孔に接触することによりシース側孔周囲が破断等するおそれがある。また、シース側孔形成部位は他の部分より脆弱であるため、側孔周囲が破断を生ずるおそれがある。また、ステント留置操作中にシース側孔形成部位において、生体器官拡張用器具の後端部側において付与したトルクおよび押し込み力（言い換えれば、プッシャビリティ）が吸収され、操作性の低下を生ずるおそれがある。そこで、本発明は、上記問題点を解決するものであり、シース開口部付近の破断等もしくは操作性の低下が生じることが少ない生体器官拡張用器具を提供するものである。

【０００４】

【課題を解決するための手段】上記目的を達成するものは、チューブ状のシャフト本体部と、該シャフト本体部の先端部に設けられた折り畳みおよび拡張可能なバルーンと、折り畳まれた状態の該バルーンを被包するように装着され、かつ該バルーンの拡張により拡張されるステントと、前記シャフト本体部の先端にて一端が開口し、他端が前記シャフト本体部の中間部にて開口するガイドワイヤールーメンとを備える拡張用カテーテルと、前記拡張用カテーテルを摺動可能に収納するカテーテルルーメンを有するシースとを備える生体器官拡張用器具である。そして、前記シースは、前記拡張用カテーテルの前記ガイドワイヤールーメンの他端側開口部付近となる位置に設けられた前記ガイドワイヤールーメンにガイドワイヤーを挿通するための軸方向に延びる側孔を備え、さらに、該シースの側孔形成部位は、剛性が前記シースの先端部より高い高剛性部となっている。

【０００５】また、前記拡張用カテーテルは、前記シース内において、前記拡張用カテーテルの前記ステントの先端が前記シース内に収納された状態から前記ステントの後端が露出する状態まで摺動可能であり、前記シースの前記側孔は、前記ステントの長さと同等もしくはそれ以上の軸方向長さを備えていることが好ましい。また、前記シースの前記側孔形成部位の先端部から前記シースの基端部まで前記シースの先端部を構成する樹脂材料より硬度の高い樹脂材料により作製されていることが好ましい。また、前記硬度の高い樹脂材料は、ショアＤ硬度５５以上の樹脂材料であることが好ましい。また、前記硬度の高い樹脂材料は、ポリエステルまたはポリアミドであることが好ましい。また、前記シースの先端部は、ショアＤ硬度５０以下の樹脂材料により作製されていることが好ましい。また、前記シースの先端部を構成する樹脂材料はポリエステルまたはポリアミドであることが好ましい。

【０００６】また、前記側孔形成部位は、金属製補強部材を有していることが好ましい。また、前記補強部材は、複数の開口を有する管状部材であることが好ましい。また、前記補強部材は、ワイヤー状部材であることが好ましい。また、前記シースは、シース外層と該シース外層の内側に形成されたシース内層とからなり、該シース内層は、フッ素系樹脂材料により作製されていることが好ましい。また、前記内層は、前記シース外層先端より突出するように作製されていることが好ましい。また、前記シースに対して前記拡張用カテーテルを任意の位置で固定するロック機構を備えていることが好ましい。また、前記拡張用カテーテルは、前記ステントよりも先端側に設けられ、前記シースの先端方向への移動を阻止するストッパーを備えることが好ましい。

【０００７】

【発明の実施の形態】本発明の生体器官拡張用器具を図面に示した好適実施例を用いて説明する。図１は、本発明の生体器官拡張用器具の一実施例の正面図、図２は、図１に示した生体器官拡張用器具の先端付近の拡大断面図、図３は、図１に示した生体器官拡張用器具の中央接合部分の拡大断面図、図４は、図１のＡ－Ａ線断面図、図５は、図１のＢ－Ｂ線断面図、図６は、図３のＣ－Ｃ線断面図、図７は、図３のＤ－Ｄ線断面図、図８は、図１に示した生体器官拡張用器具の分岐ハブの拡大断面図、図９は、図１に示した生体器官拡張用器具の拡張用カテーテルの後端部の拡大断面図、図１０は、本発明の生体器官拡張用器具の他の実施例を説明するための説明図である。

【０００８】本発明の生体器官拡張用器具１は、チューブ状のシャフト本体部２１と、シャフト本体部２１の先端部に設けられた折り畳みおよび拡張可能なバルーン３と、折り畳まれた状態のバルーン３を被包するように装着され、かつバルーン３の拡張により拡張されるステント４と、シャフト本体部２１の先端にて一端が開口し、他端がシャフト本体部２１の中間部にて開口するガイドワイヤールーメン１５とを備える拡張用カテーテル１０と、拡張用カテーテル１０を摺動可能に収納するカテーテルルーメン５０を有するシース５とを備える。そして、シース５は、拡張用カテーテル１０のガイドワイヤールーメン１５の他端側開口部付近となる位置に設けられたガイドワイヤールーメン１５にガイドワイヤー１００を挿通するための軸方向に延びる側孔５１を備え、さらに、シースの側孔形成部位５２ｂは、剛性がシース５の先端部５２ａより高い高剛性部となっている。

【０００９】本発明の生体器官拡張用器具１は、いわゆるラピッドエクスチェンジタイプと呼ばれるものであり、図１、図３に示すように拡張用カテーテル１０内部に設けられ、かつ、拡張用カテーテル１０の先端と中間部において開口（他端側開口部３６）したガイドワイヤールーメン１５と、シース中間部に形成されたガイドワイヤー挿通用の側孔５１を有している。このような構成により、生体器官拡張用器具１は、シースの途中（中間部）からシースの側孔を通じてカテーテル中間部に形成された開口（他端側開口部３６）にガイドワイヤーを挿入して、ステント操作を行うことができるものとなって

いる。

【００１０】生体器官拡張用器具１は、図１に示すように、シャフト本体部２１と、シャフト本体部２１先端に設けられたストッパー６と、シャフト本体部２１の先端部に設けられたステント拡張用のバルーン３と、バルーン３上に装着されたステント４と、シャフト本体部２１の後端部に取り付けられたハブ８とからなる拡張用カテーテル１０と、カテーテル１０を被包するシース５と、シース５の後端部に取り付けられた分岐ハブ６０とからなる。

【００１１】拡張用カテーテル１０は、先端側シャフト部１０ａと後端側シャフト部１０ｂとからなり、先端側シャフト部１０ａと後端側シャフト部１０ｂは図１、図３に示すように接合コネクター７を介して接合されている。また、拡張用カテーテル１０は、シース５内において、拡張用カテーテル１０のステント４の先端がシース５内に収納された状態からステント４の後端が露出する状態まで摺動可能である。先端側シャフト部１０ａは、図２、図３に示すようにガイドワイヤールーメン１５を形成する内管１２と、内管１２の先端部に設けられたバルーン３と、バルーン３の外周に装着されたステント４と、バルーン３より後端側に設けられ、内管１２を被包し、内管１２の外面との間にバルーン拡張用ルーメン１６を形成する外管１３とからなる。そして、先端側シャフト部１０ａはシース５のカテーテルルーメン５０内に摺動可能に収納されている。そして、先端側シャフト部１０ｂの後端部は、接合コネクター７の先端部と接合している。

【００１２】バルーン３は、図２に示すように、先端側接合部３ａおよび後端側接合部３ｂを有し、先端側接合部３ａが内管１２の先端より若干後端側の位置に固定され、後端側接合部３ｂが外管１３の先端に固定されている。また、バルーン３は、基端部付近にてバルーン拡張用ルーメン１６と連通している。そして、内管１２の先端には、バルーン３の先端側接合部３ａの先端部を被包するようにストッパー６が固定されている。ストッパー６は、弾性材料により環状に形成されており、後端部の外径がシース５の内径とほぼ等しいか若干大きいものとなっている。このようにストッパー６を有することにより、ステント４の先端方向への移動が阻止されステント留置操作中にカテーテルからステント４が脱落することがない。また、ストッパー６は、先端に向かってなだらかに縮径するテーパー状となっている。このように形成することにより、ストッパー６に狭窄部への誘導機能を持たせることができ、ステント装着部分を生体器官の狭窄部への挿入が容易となる。

【００１３】そして、内管１２としては、外径が０．３５～１．０mm、好ましくは０．４５～０．８mmであり、内径が０．２～０．９mm、好ましくは０．３５～０．７mmである。外管１３としては、外径が０．６～１．５mm、好ましくは０．８～１．１mmであり、内径が０．５～１．４mm、好ましくは０．７～１．０mmである。シース５としては、外径が０．８～１．８mm、好ましくは１．２～１．５mmであり、内径が０．５～１．５mm、好ましくは１．０～１．３mmである。内管１２、外管１３ならびにストッパー６の形成材料としては、ある程度の可撓性を有するものが好ましく、例えば、ポリアミド、ポリエステル、ポリオレフイン（架橋もしくは部分架橋物も含む）、ポリ塩化ビニル、ポリウレタン等の熱可塑性樹脂、シリコーンゴム、ラテックスゴム等が使用でき、好ましくは上記の熱可塑性樹脂である。

【００１４】バルーン３は、折り畳み可能なものであり、拡張させない状態では、内管１２の外周に折り畳まれた状態となることができるものである。バルーン３は、装着されるステント４を拡張できるようにほぼ同一径の筒状部分（好ましくは、円筒部分）となった拡張可能部３１を有している。上記の略円筒部分は、完全な円筒でなくてもよく、多角柱状のものであってもよい。そして、バルーン３は、上述のように、先端側接合部３ａが内管１２にまた後端側接合部３ｂが外管１３の先端に接着剤または熱融着などにより液密に固着されている。バルーン３は、図２に示すように、バルーン３の内面と内管１２の外面との間に拡張空間３ｃを形成する。この拡張空間は、後端部ではその全周において拡張用ルーメン１６と連通している。このように、バルーン３の後端は、比較的大きい容積を有する拡張用ルーメンと連通しているので、拡張用ルーメン１６よりバルーン内への拡張用流体の注入が確実である。

【００１５】バルーン３の形成材料としては、ある程度の可撓性を有するものが好ましく、例えば、ポリオレフイン、ポリ塩化ビニル、ポリアミド、ポリウレタン、ポリエステル、ポリアリレーンサルファイド等の熱可塑性樹脂、シリコーンゴム、ラテックスゴム等が使用できる。特に、延伸可能な材料であることが好ましく、バルーン３は、高い強度および拡張力を有する２軸延伸されたものが好ましい。バルーン３の大きさとしては、拡張されたときの円筒部分（拡張可能部３１）の外径が、１．５～５．０mm、好ましくは２．５～４．０mmであり、長さが５～５０mm、好ましくは１０～４０mmである。また、先端側接合部３ａの外径が、０．５～１．５mm、好ましくは０．７～１．０mmであり、長さが１～５mm、好ましくは１．０～１．３mmである。また、後端側接合部３ｂの外径が、０．８～１．６mm、好ましくは１．０～１．５mmであり、長さが１～５mm、好ましくは２～４mmである。

【００１６】そして、シャフト本体部２１（この実施例では、内管１２）には、バルーン３の拡張可能部３１の内部の先端付近となる位置の外面に先端側造影マーカー１７が固定されている。同様に、シャフト本体部２１

（この実施例では、内管１２）には、バルーン３の拡張可能部３１の内部の後端付近となる位置の外面に後端側造影マーカー１８が固定されている。造影マーカーは、X線不透過材料（例えば、金、白金、タングステンあるいはそれらの合金、あるいは銀－パラジウム合金等）により形成することが好ましい。このようにすることによりバルーン３の拡張可能部３１の先端および後端の位置、ひいては、ステント４の先端および後端の位置をX線造影により確認することができる。

【００１７】本発明の生体器官拡張用器具１に使用されるステント４は、略管状体に形成され、生体内への挿入のための直径を有し、管状体の内部より半径方向外方に広がる力が付加されたとき、言い換えれば、バルーン３が拡張したときに拡張可能（伸張可能）なものであり、いわゆるバルーンエキスパンダブルステントである。ステント４としては、例えば、図１４に示すように、ステント４の軸方向に長くかつ中央部が閉口した略楕円状もしくは多角形状の構成要素２２が、ステント４の中心軸に対してほぼ等角度間隔にて略円周上に配列されかつ、構成要素の円周方向の隣接部（側部）間が接続部２３（２３ａ，２３ｂ，２３ｃ，２３ｄ）にて接続された環状ユニット２４（２４ａ，２４ｂ，２４ｃ，２４ｄ，２４ｅ，２４ｆ）からなり、かつ、複数の環状ユニット２４ａ，２４ｂ，２４ｃ，２４ｄ，２４ｅ，２４ｆがステント４の軸方向に並んでいる。さらに、一つの環状ユニット４の接続部２３と隣り合う環状ユニット２４の接続部２３とが連結部２５（２５ａ，２５ｂ，２５ｃ，２５ｄ，２５ｅ）により少なくとも１カ所連絡されているものが好適である。しかし、ステント４の形状はこのようなものに限定されるものではなく、網目状などの公知のものが使用できる。

【００１８】ステント４の形成材料としては、ある程度の生体適合性を有するものが好ましく、例えば、ステンレス鋼、タンタルもしくはタンタル合金、プラチナもしくはプラチナ合金、金もしくは金合金、コバルトベース合金等が考えられる。またステント形状を作製した後に貴金属メッキ（金、プラチナ）をしてもよい。ステンレス鋼としては、最も耐腐食性のあるＳＵＳ３１６Ｌが好適である。ステント４の非拡張時の直径は、０．８～１．５mm程度が好適であり、特に、０．９～１．２mmがより好ましい。

【００１９】後端側シャフト部１０ｂは、図１、図３に示すように、シャフトチューブ３２と、シャフトチューブ３２の後端に固定されたハブ８とからなる。そして、後端側シャフト部１０ｂはシース５のカテーテルルーメン５０内に摺動可能に収納されている。そして、後端側シャフト部１０ｂの先端部は、接合コネクター７の後端部と接合している。シャフトチューブ３２内には、図１、図７に示すように剛性付与体３３が挿入されており、剛性付与体３３は後端部にてシャフトチューブ３２に固定され、先端は、シャフトチューブ３２の先端より突出し、後述する接合コネクター７を貫通し、先端側シャフト内に延びている。この実施例では、剛性付与体３３の先端部は、先端側シャフトの内管１２と外管１３との間、言い換えれば、バルーン拡張用ルーメン１６内に到達している。

【００２０】剛性付与体３３は、シャフトチューブ３２の基端より、その内部を先端側に延びている。また、剛性付与体３３は、シャフト本体部２１の湾曲の障害とならないように、基端部のみシャフトチューブ３２もしくはハブ８に固定されており、その他の部分、具体的には、シャフトチューブ３２の基端部を除く内部、接合コネクター７部分、先端側シャフト部（内管１２および外管１３）のいずれにも固定されていない。剛性付与体３３は、シャフトチューブ３２の可撓性をあまり低下させることなく、屈曲部位でのシャフトチューブ３２の極度の折れ曲がり、シャフトチューブ３２の血管内での蛇行を防止する。剛性付与体３３は、線状体により形成されていることが好ましい。線状体としては、金属線であることが好ましく、線径０．０５～１．５mm、好ましくは０．１～１．０mmのステンレス鋼等の弾性金属、超弾性合金などであり、特に好ましくは、ばね用高張力ステンレス鋼、超弾性合金線である。

【００２１】ここでいう超弾性合金とは一般に形状記憶合金といわれ、少なくとも生体温度（３７℃付近）で超弾性を示すものである。特に好ましくは、４９－５３原子％ＮｉのＴｉ－Ｎｉ合金、３８．５－４１．５重量％ＺｎのＣｕ－Ｚｎ合金、１－１０重量％ＸのＣｕ－Ｚｎ－Ｘ合金（Ｘ＝Ｂｅ、Ｓｉ、Ｓｎ、Ａｌ、Ｇａ）、３６－３８原子％ＡｌのＮｉ－Ａｌ合金等の超弾性合金が好適に使用される。特に、上記のＴｉ－Ｎｉ合金が望ましい。また、Ｔｉ－Ｎｉ合金の一部を０．０１～１０．０原子％Ｘで置換したＴｉ－Ｎｉ－Ｘ合金（Ｘ＝Ｃｏ，Ｆｅ，Ｍｎ，Ｃｒ，Ｖ，Ａｌ，Ｎｂ，Ｗ，Ｂなど）とするか、またはＴｉ－Ｎｉ合金の一部を０．０１～３０．０原子％Ｘで置換したＴｉ－Ｎｉ－Ｘ合金（Ｘ＝Ｃｕ，Ｐｂ，Ｚｒ）とすること、また、冷間加工率または／および最終熱処理の条件を選択することにより、機械的特性を適宜変えることができる。また、上記のＴｉ－Ｎｉ－Ｘ合金を用いて冷間加工率および／または最終熱処理の条件を選択することにより、機械的特性を適宜変えることができる。

【００２２】シャフトチューブ３２は、基端において剛性付与体３３を固定しており、さらに、このシャフトチューブ３２の後端は、ハブ８の先端部に固定されている。ハブ８とシャフトチューブ３２の境界部の外面には、両者を被覆するように、キンク防止用のチューブ３５が取り付けられている。また、ハブ８の後端部は、バルーン拡張用流体注入器具（例えば、シリンジ）の接続部３４となっている。シャフトチューブ３２としては、

外径が０．５～１．５ｍｍ、好ましくは０．６～１．３ｍｍであり、内径が０．３～１．４ｍｍ、好ましくは０．５～１．２ｍｍである。シャフトチューブ３２の形成材料としては、ある程度の可撓性を有するものが好ましく、例えば、ポリオレフイン（例えば、ポリエチレン、ポリプロピレン、エチレン－プロピレン共重合体、エチレン－酢酸ビニル共重合体など）、ポリ塩化ビニル、ポリアミドエラストマー、ポリイミド、ポリウレタン等の熱可塑性樹脂、シリコーンゴム、ラテックスゴム等が使用でき、好ましくは上記の熱可塑性樹脂である。また、シャフトチューブ３２の形成材料としては、剛性付与体３３を用いずに、ステンレス管を用いてもよい。

【００２３】接合コネクター７は、図３に示すように、先端中心より中央部へ軸方向に延び、中央部から湾曲し後端側の外側面に到達する内管挿通路を備え、この挿通路内を内管１２の後端部は貫通し、接合コネクター７の側面より突出する内管１２の後端部が、ガイドワイヤー導入口３６（他端側開口部３６）を形成している。また、他端側開口部３６の開口は、図３の基端側斜め上方に向かって形成されている。なお、開口の向きは実施例のものに限られず、図３の真上に向かって形成されていてもよい。また、接合コネクター７には、先端から基端に延びるバルーン拡張用流体流通路３７ａ、３７ｂが形成されている。この流通路により、内管１２と外管１３の間により形成されているバルーン拡張用ルーメン１６とシャフトチューブ３２内に形成されているバルーン拡張用ルーメン１６とは連通している。また、上述のように、接合コネクター７には、先端より基端まで貫通した剛性付与体導通路が形成されており、これを剛性付与体３３は貫通している。

【００２４】シース５は、図１、図２および図３に示すようにチューブ状に作製され、内部にカテーテルルーメン５０と、中間部に側孔５１とを備えている。また、ステント４の先端をカテーテルルーメン５０内に収納した状態ではステント４の先端部とストッパー６の後端とはほぼ接触している。また、シース５の後端部は、分岐ハブ６０の先端部と接合している。カテーテルルーメン５０は、図１，図３に示すように拡張用カテーテル１０を摺動可能に収納する通路となっている。言い換えれば、カテーテルルーメン５０は、拡張用カテーテル１０の挿通を可能とする通路であり、カテーテルルーメンの先端、つまり、シースの先端より、拡張用カテーテル１０の先端は突出し、カテーテルルーメンの後端、つまり、シースの後端より、拡張用カテーテル１０の基端部は突出している。

【００２５】側孔５１は、ガイドワイヤールーメン１５内にガイドワイヤー１００を挿通するために設けられている。ガイドワイヤー１００は、側孔５１を介して他端側開口部３６に挿通されガイドワイヤールーメン１５内に導入される。側孔５１は、図１、図３に示すように軸方向に延びる楕円状開口部として作製され、ガイドワイヤールーメン１５のガイドワイヤー挿入口である他端側開口部３６付近となる位置にカテーテルルーメン５０と連通するように形成されている。

【００２６】また、拡張用カテーテル１０は、シース５内において、拡張用カテーテル１０のステント４の先端がシース５内に収納された状態からステント４の後端が露出する状態まで摺動可能であり、シース５の側孔５１は、ステント４の長さと同等もしくはそれ以上の軸方向長さを備えている。このように、側孔５１が軸方向にある程度の長さを有していることにより、他端側開口部３６（ガイドワイヤー挿入口）が側孔５１内に位置した状態でステント４の後端をシース外に完全に露出可能となる。具体的には、図１１に示すようにステント４の先端がシース内に収納された状態においては、他端側開口部３６の基端３６ａは側孔５１の基端より先端側に位置しており、図１２に示すようにステント４がシース５先端から完全に露出した状態においては、他端側開口部３６の基端３６ａは側孔５１の先端より基端側に位置するものとなる。なお、この状態においては、他端側開口部３６の先端３６ｂも側孔５１の先端より基端側に位置するように構成されていることが好ましい。このため、ステント留置操作中にガイドワイヤー１００が側孔５１に接触しにくいため側孔形成部位は破損しにくいものとなる。

【００２７】また、生体内挿入時には、生体器官拡張用器具１は、図１に示すように、シース５の先端より、拡張用カテーテルのストッパー６部分の殆どが露出し、かつ、ステント４は全く露出しない状態となっており、この状態において、拡張用カテーテル１０は、後述するシース５の後端部に設けられた分岐ハブ６０のカテーテルロック機構６３により固定されている。このため、カテーテルロック機構６３を解除しない限り、図１の状態が維持されると共に、シース内を拡張用カテーテルは摺動不能である。また、拡張用カテーテル１０は、シース５内において、カテーテルロック機構６３によりロックされていない状態において、拡張用カテーテル１０のステント４の先端がシース５内に収納された状態からステント４の後端が露出する状態まで摺動可能である。

【００２８】シース５は、図１～図３、図１０～図１２に示すように、シース外層５２と、シース外層５２の内側に形成されたシース内層５３とから形成されている。シース外層５２とシース内層５３は一体化している。そして、図１、図２に示すように、シース外層５２の先端とシース内層５３の先端は、シースの軸方向にほぼ同じ位置となるように作製されている。また、図８に示すように、シース外層５２とシース内層５３の基端は分岐ハブ６０の先端部に接着剤、熱融着等により接合されている。なお、実施例では、外層と内層の２層構造として作製されているが、３層以上の多層構造であってもよい。

また、シースは、単層構造であってもよい。

【００２９】シース内層５３は、フッ素系樹脂材料により形成されていることが好ましい。フッ素系樹脂材料としては、ポリテトラフルオロエチレン（ＰＴＦＥ）、エチレンテトラフルオロエチレン（ＥＴＦＥ）等が使用でき、好ましくは、ポリテトラフルオロエチレンである。シース内層をフッ素系樹脂材料により作製することにより、カテーテルルーメン内壁は滑りやすくなり、カテーテルルーメン内において拡張用カテーテルは容易に摺動するものとなる。シース外層５２は、曲折した生体内管腔を容易に進行可能なようにある程度可撓性を有する樹脂により作製されていることが好ましい。シース外層５２の構成材料としては、例えば、ポリアミド、ポリエステル、ポリオレフイン（架橋もしくは部分架橋物も含む）、ポリ塩化ビニル、ポリウレタン等の熱可塑性樹脂等が使用でき、好ましくは上記の熱可塑性樹脂である。

【００３０】また、シース５の側孔形成部位（側孔周囲部分）は、剛性がシース５の先端部より高い高剛性部となっている。このように構成することにより、ステント留置操作中において、側孔形成部位の破断等もしくは側孔形成部位における生体器官拡張用器具の後端部側において付与したトルクおよび押し込み力（言い換えれば、プッシャビリティ）の吸収による操作性の低下が生じにくい。具体的には、シース５（シース外層５２）の側孔形成部位５２ｂの先端部からシース５（シース外層５２）の基端部５２ｃまでシース５（シース外層５２）の先端部５２ａを構成する樹脂材料より硬度の高い樹脂材料により作製されている。

【００３１】硬度の高い樹脂材料は、ショアＤ硬度５０以上の樹脂材料であることが好ましく、特に、ショアＤ硬度５５以上であることが好ましい。また、硬度の高い樹脂材料は、ポリエステル、ポリアミドであることが好ましい。ポリエステル系樹脂としては、ポリエチレンテレフタレート、ポリブチレンテレフタレート等が好適であり、好ましくは、ポリエチレンテレフタレートである。また、ポリアミド系樹脂としては、ナイロン６、ナイロン６６、ナイロン４６、ナイロン１１、ナイロン１２等が好適である。また、シースの先端部５２ａは、ショアＤ硬度５０以下の樹脂材料により作製されていることが好ましい。これにより、シースの先端部は柔軟性を有するものとなり、入り組んだ生体管腔をスムーズに進行することができる。また、シース先端部５２ａを構成する樹脂材料は、ポリエステルエラストマー、オレフィン系エラストマー（例えば、ポリエチレンエラストマー、ポリプロピレンエラストマー）、ポリアミドエラストマー、スチレン系エラストマー（例えば、スチレン－ブタジエン－スチレンコポリマー、スチレン－イソプレン－スチレンコポリマー、スチレン－エチレンブチレン－スチレンコポリマー）、ポリアミドエラストマー、ポリエステルエラストマー、熱可塑性フッ素系エラストマーなどの可撓性樹脂が好ましい。

【００３２】シース５は、例えば、シース先端部５２ａがショアＤ硬度５０以下のポリアミドエラストマーにより、かつ、側孔周囲５２ｂがショアＤ硬度５０以上のポリアミドエラストマーにより、かつ、シース基端部５２ｃがショアＤ硬度５０以上のポリアミドエラストマーにより作製することができる。以上のようにシースを構成することにより、ガイドワイヤーを側孔５１を通じて他端開口部３６に挿入してステント留置操作を行っても、側孔形成部位５２ｂは破断等することなく、また、生体器官拡張用器具の後端部側において付与したトルクおよび押し込み力（言い換えれば、プッシャビリティ）が側孔形成部位５２ｂにより吸収されることに起因する操作性の低下を生ずるおそれがない。なお、実施例では、シース５の先端部５２ａ、シース５の側孔形成部位５２ｂ、シース５の基端部５２ｃをそれぞれ別の構成部分として作製した後接合して一体化してシースを作製しているが、これに限られるものではなく、側孔形成部位５２ｂと基端部５２ｃを一つの構成部分として作製して先端部５２ａと接合してシースを作製してもよい。接合は、熱融着、接着剤等により行うことができる。

【００３３】また、シース先端部５２ａの外面は親水化処理が行われていることが好ましい。親水化処理としては、シース外面に親水性物質（例えば、水溶性シリコーン、ＰＶＡ、ＰＶＰなど）をコーティングすることにより行うことができる。シースの大きさとしては、外径が０．８～１．８ｍｍ、好ましくは、１．２～１．５ｍｍ、内径が０．８～１．５ｍｍ、好ましくは、１．０～１．３ｍｍ、長さが８００～１６００ｍｍ、好ましくは、１２００～１４００ｍｍである。シースの側孔５１の大きさとしては、シースの軸方向の長さが、５～８０ｍｍ、好ましくは、１５～５０ｍｍ、シースの軸方向に直交する方向の長さが、０．１～１．０ｍｍ、好ましくは、０．３５～０．７ｍｍである。

【００３４】また、図１０に示す実施例の生体器官拡張用器具のように、シース５の側孔形成部位５２ｂは、金属製補強部材５４を有していてもよい。側孔形成部位に金属補強部材を設けることによりシース側孔５１周囲の破断、側孔形成部位におけるトルク等の吸収を防止することができる。金属製補強部材５４は、図１３に示すように、複数の開口５４１を有する管状部材であることが好ましい。金属補強部材は、ほぼ同一径の管状部材として作製されており、管状部材の軸方向に沿って延びる複数の楕円形状の開口５４１を有している。開口部形状としては楕円形状に限られず、長方形状等であってもよい。管状部材は、側孔形成部位５２ｂのシース外層壁に内層５３と接触するとともに、管状部材の複数の開口のうち一つの開口が側孔５１と重なるように設置されている。管状部材の埋め込み方法としては、芯金の表面に内層形成材料が被覆されたものの上に基端側の外層を先端

部分以外の部分に形成し、外層非形成部分の基端部上に管状部材を嵌めて取り付け、その上に側孔形成部位用の樹脂を被覆し、さらに、外層非形成部分の先端部上に先端部形成部用の樹脂を被覆することにより作製することにより行うことができる。

【００３５】また、金属補強部材としては、図示しないが、ワイヤー状部材により作製されているものであってもよい。ワイヤー状部材の場合は、直線状ワイヤーを側孔周囲５２ｂのシース壁材にシースの軸方向に沿って複数本埋め込むことが好ましい。また、ワイヤー状部材をコイル状もしくはブレード状に作製して、それを側孔５１付近のシース内壁に埋め込んでもよい。また、直線状ワイヤーと、コイル状ワイヤーを組み合わせて金属製補強部材を形成してもよい。金属補強部材の構成材料としては、剛性付与体３３と同様の材料を使用することが好ましい。管状部材の金属製補強部材の大きさとしては、長さが１０～９０mm、好ましくは、２０～６０mmであり、内径が、０．９～１．６mm、好ましくは、１．１～１．４mmであり、壁材の肉厚が、０．０３～０．１５mm、好ましくは、０．０５～０．１０mmである。ワイヤー状部材の金属補強部材の線径としては、０．０３～０．１５mmであり、好ましくは、０．０５～０．１０mmである。

【００３６】また、シース外面は親水化処理が行われていることが好ましい。これにより、シースが生体管腔または体腔を移動する際に内壁を損傷にしくい。親水化処理としては、シース外面に親水性物質（例えば、水溶性シリコーン、ＰＶＡ、ＰＶＰなど）をコーティングすることにより行うことができる。また、図１５に示す実施例の生体器官拡張用器具７０のように、シース５は、シース内層７３がシース外層７２より先端側に突出するように作製されていてもよい。このように先端側に突出するように作製することにより、シースの肉厚を薄くできるとともに、シースの先端部の外径を小径にすることができる。このようなシース内層７３としては、上述したようにフッ素系樹脂により作製されていることが好ましい。また、シース内層の突出部分の外面には親水化処理が行われていることが好ましい。シース内層７３の先端突出部分の長さは、０．５～５０mm、好ましくは、１０～４０mmである。また、シースの内層７３のうち、側孔形成部位付近を除いてフッ素系樹脂により作製してもよい。

【００３７】次に分岐ハブ６０について、図８を用いて説明する。分岐ハブ６０は、図８に示すように、分岐ハブ本体部６１と、分岐ハブ本体部６１の中央部に本体部６１から分岐するように設けられたプライミング用のインジェクションポート６２と、分岐ハブ６０の後端部に設けられ拡張用カテーテルの移動を制限するカテーテルロック機構６３と、分岐ハブの先端から基端まで設けられた拡張用カテーテルルーメン６４とからなる。また、分岐ハブ６０の後端６５のカテーテルルーメン径は、ハブ８の先端部より小さく作製されており、ハブ８の先端部は、分岐ハブ６０の後端付近から先端に移動しないものとなっている。また、分岐ハブ６０の先端部には、シース後端部が接合されている。シース５の後端部は、分岐ハブ６０の先端部から基端側に１～５mmの位置に固定されていることが好ましい。

【００３８】ロック機構６３は、圧縮により拡張用カテーテル１０の基端部を挟持する弾性体６３１と弾性体６３１を圧縮する操作体６３２とからなる。ロック機構６３を備えることにより、拡張用カテーテル１０はシース５に対して任意の位置で固定される。弾性体６３１は、分岐ハブ本体部６１の基端部に設けられた凹部６１１内に設置されており、弾性体６３１の内部にはカテーテルルーメン６４の一部を形成するルーメン６３１ａが形成されている。また、本体部凹部６１１の内径は、弾性体６３１外径より一回り大きく作製されており、弾性体６３１が操作体６３２により圧縮された際の弾性体の半径方向への拡径を可能にしている。弾性体６３１のルーメン６３１ａは、軸方向に２つの略球形状が一部重なり合った形状に作製されており、両端と中央部が縮径している。なお、ルーメン６３１ａは、上述した実施例の形状に限られるものではなく、拡張用カテーテルを的確にロックするものであれば、いかなる形状であってもよい。

【００３９】操作体６３２は、中央部に先端側に突出した弾性体押圧部６３２ａと、その外周に形成され、かつ、凹部６１１の後端部６１１ａと螺合する螺合部６３２ｂと、螺合部６３２ｃの外周に形成され操作体６３２を回転させる際に担持するための担持部６３２ｃとからなる。また、弾性体押圧部６３２ａの内部には、カテーテルルーメン６４の一部を形成するルーメン６３２ｄが形成されている。また、弾性体押圧部６３２ａの先端側部分は、図８に示すように本体部凹部６１１内に収納されており、操作体の先端への移動により弾性体６３１を圧縮するものとなっている。以上のような構成により、操作体６３２を回転させ分岐ハブ６０に対して先端側に螺合した場合、弾性体押圧部６３２ａの先端は弾性体６３１の後端に接触して、さらに、操作体６３２を先端側に螺合することにより弾性体６３１は軸方向に圧縮される。そして、圧縮するにつれてルーメン６３１ａ内径は小さくなり最終的に弾性体６３１により拡張用カテーテル１０の基端部が固定される。なお、ロック機構６３の解除は、上記と逆の回転操作により行われる。

【００４０】弾性体６３１を除く分岐ハブ６０の構成材料としては、ポリカーボネート、ポリオレフィン（例えば、ポリエチレン、ポリプロピレン、エチレンープロピレンコポリマー）、スチレン系樹脂［例えば、ポリスチレン、ＭＳ樹脂（メタクリレートースチレン共重合体）、ＭＢＳ樹脂（メタクリレートーブチレンースチレン共重合体）］、ポリエステルなどが使用できる。弾性

体６３１の構成材料としては、ウレタンゴム、シリコーンゴム、ブタジエンゴムなどの合成ゴム、ラテックスゴムなどの天然ゴム、オレフィン系エラストマー（例えば、ポリエチレンエラストマー、ポリプロピレンエラストマー）、ポリアミドエラストマー、スチレン系エラストマー（例えば、スチレン－ブタジエン－スチレンコポリマー、スチレン－イソプレン－スチレンコポリマー、スチレン－エチレンブチレン－スチレンコポリマー）、ポリウレタン、ウレタン系エラストマー、フッ素樹脂系エラストマー等が好ましい。

【００４１】なお、本発明の実施例では、シース５は分岐ハブ６０の先端部に直接固定されているがこれに限られるものではなく、シース５後端部にハブを取り付け、それを分岐ハブ６０の先端部と螺合することによりシースと分岐ハブを接合してもよい。また、ステント４をシース内に収納した状態（カテーテル１０を基端側に引いた状態）で分岐ハブ６０の後端部はキンク防止用のチューブ３５の先端部から１０～２００mm、好ましくは５０～１００mmの位置で固定されている。

【００４２】次に、本発明の生体器官拡張用器具の作用について説明する。図１１に示すように、ステント４先端がシース５内に収納された状態では、他端側開口部３６の開口基端３６ａは側孔５１基端の先端側近傍に位置している。そして、拡張用カテーテル１０はロック機構６３により固定され移動が制限されている。この状態において、側孔５１を通じて他端側開口部３６にガイドワイヤー１００を挿入した後、インジェクションポート６２から生理食塩水等プライミング液を注入し拡張用カテーテルルーメン５０内をプライミングする。ストッパー６の後端部とシース５の先端部とが接触しているためシース先端からプライミング液が漏れないものとなっている。そしてガイディングカテーテル（図示せず）を介して生体器官拡張用カテーテル１０を体腔内に挿入しガイドワイヤー１００に沿って目的部位に誘導する。

【００４３】生体器官拡張用器具１の先端が目的部位付近に到達した後、一方の手で分岐ハブ６０を保持し、ロック機構６３を解除して拡張用カテーテル１０をシース５に対して先端側に押し出しステント４を露出する。ステント４が完全に露出した状態では、図１２に示すように、他端側開口部３６の開口先端３６ｂは、側孔５１の先端の基端側近傍に位置している。その後、ステント４を目的部位にて拡張、留置して操作を終了する。以上、生体器官拡張用器具について説明したが、生体器官拡張用器具の構成は上述したものに限られるものではない。

【００４４】

【発明の効果】本発明の生体器官拡張用器具は、チューブ状のシャフト本体部と、該シャフト本体部の先端部に設けられた折り畳みおよび拡張可能なバルーンと、折り畳まれた状態の該バルーンを被包するように装着され、かつ該バルーンの拡張により拡張されるステントと、前記シャフト本体部の先端にて一端が開口し、他端が前記シャフト本体部の中間部にて開口するガイドワイヤールーメンとを備える拡張用カテーテルと、前記拡張用カテーテルを摺動可能に収納するカテーテルルーメンを有するシースとを備える生体器官拡張用器具であって、前記シースは、前記拡張器具の前記ガイドワイヤールーメンの他端側開口部付近となる位置に設けられた前記ガイドワイヤールーメン内にガイドワイヤーを挿通するための軸方向に延びる側孔を備え、さらに、該シースの側孔形成部位は、剛性が前記シースの先端部より高い高剛性部となっている。このため、本発明の生体拡張用器具では、シース側孔形成部位での破断、生体器官拡張用器具の後端部側において付与したトルクおよび押し込み力（言い換えれば、プッシャビリティ）のシース側孔形成部位での吸収に起因する操作性の低下が少ない。

【図面の簡単な説明】

【図１】図１は、本発明の生体器官拡張用器具の一実施例の正面図である。

【図２】図２は、図１に示した生体器官拡張用器具の先端付近の拡大断面図である。

【図３】図３は、図１に示した生体器官拡張用器具の中央接合部分の拡大断面図である。

【図４】図４は、図１のＡ－Ａ線断面図である。

【図５】図５は、図１のＢ－Ｂ線断面図である。

【図６】図６は、図３のＣ－Ｃ線断面図である。

【図７】図７は、図３のＤ－Ｄ線断面図である。

【図８】図８は、図１に示した生体器官拡張用器具の分岐ハブの拡大断面図である。

【図９】図９は、図１に示した生体器官拡張用器具の拡張カテーテルの後端部の拡大断面図である。

【図１０】図１０は、本発明の生体器官拡張用器具の他の実施例を説明するための説明図である。

【図１１】図１１は、本発明の生体器官拡張用器具の実施例を説明するための説明図である。

【図１２】図１２は、本発明の生体器官拡張用器具の実施例を説明するための説明図である。

【図１３】図１３は、シース側孔周囲に設置される補強部材の実施例の斜視図である。

【図１４】図１４は、本発明の生体器官拡張用器具に使用されるステントの実施例を示す斜視図である。

【図１５】図１５は、本発明の生体器官拡張用器具の他の実施例を説明するための説明図である。

【符号の説明】

1　生体器官拡張用器具
3　バルーン
4　ステント
5　シース
6　ストッパー
7　接合部
8　ハブ

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１０　拡張用カテーテル
１０ａ　先端側シャフト部
１０ｂ　後端側シャフト部
１５　ガイドワイヤールーメン
２１　シャフト本体部
５０　カテーテルルーメン

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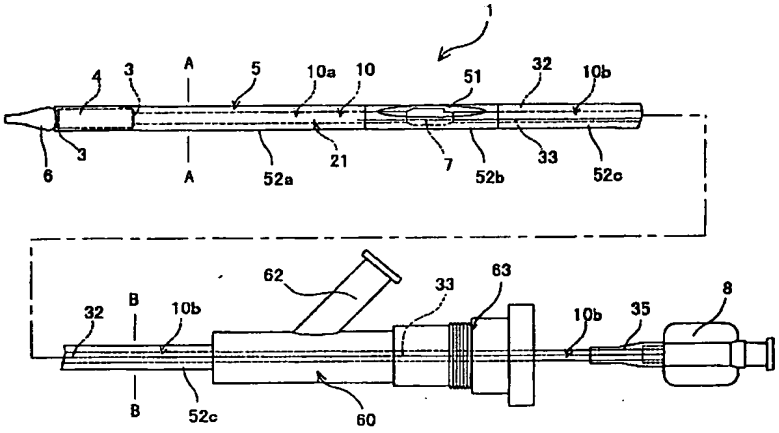
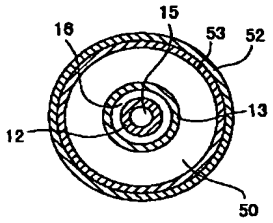
＊５２　外層
５２ｂ　側孔形成部位
５３　内層
５４　金属補強部材
６０　分岐ハブ
＊

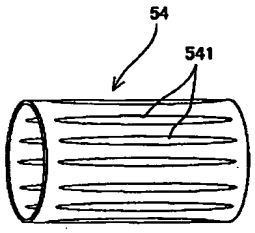
【図１】



【図４】



【図１３】



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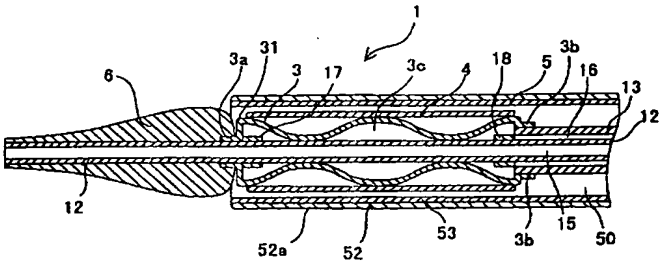

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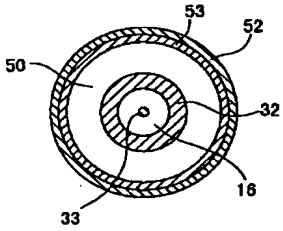
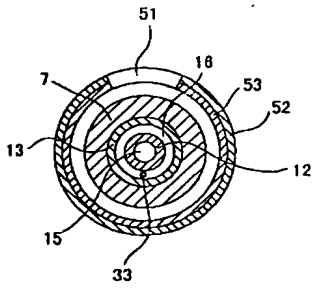


【図６】



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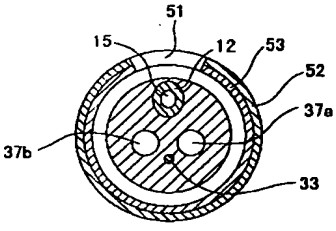
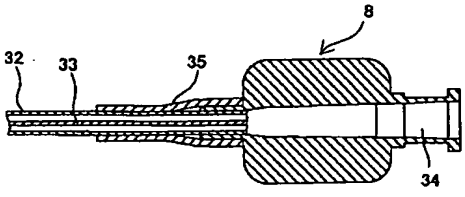


【図９】



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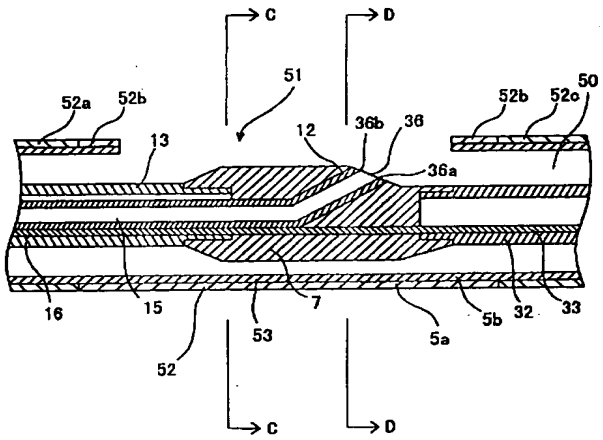
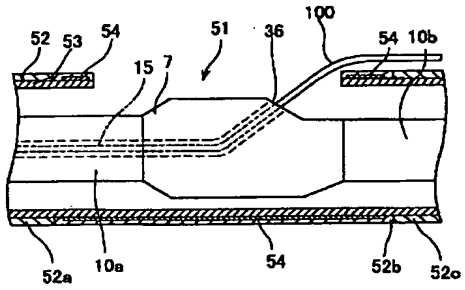
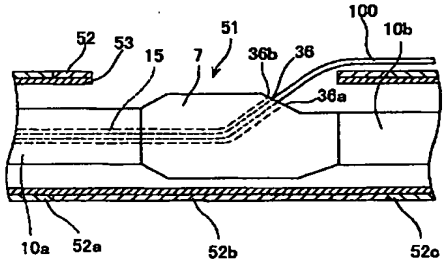


【図１０】



【図１１】



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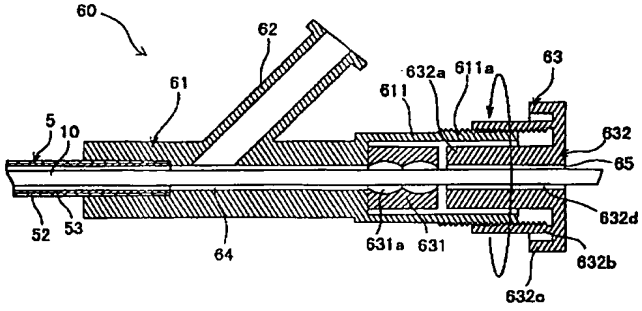
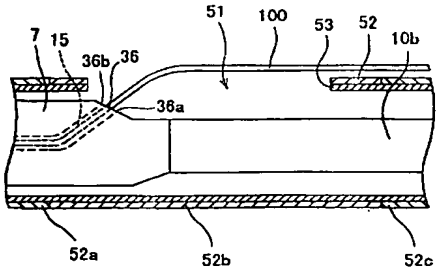
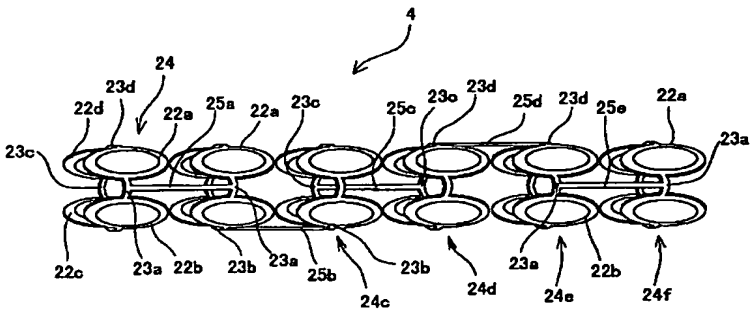


【図１２】



【図１４】



【図１５】